Guide on How to Prepare an Informed Consent

(unofficial translation)

Note: The informed consent must be in the subject's mother tongue

General

When recruiting research subjects, adequate information about the rights of the subjects, the purpose and nature of the research, the methods used, the processing of personal data and the potential risks and harms associated with the research must be given to research subject. The explanation must be provided in such a way that the research subject is able to decide on his or her consent in full knowledge of the facts relating to the research that affect his or her decision-making.

The information given to the research subject must be adequate, short and to the point (5 pages maximum recommended) and written in a language that the subject understands. If foreign language words or expressions are to be used (e.g. for clarity), they should be explained when first mentioned. In addition, the font of text used should be a sufficiently large at size.

Commanding, instructive, and attractive language should be avoided in the informed consent.

If informed consent is asked from the research subject's representative, the form of address in the document should be changed accordingly. In such cases, separate documents should be drawn up for minors or subjects with reduced capacity for self-determination. They should be written in a language that is easily understood by the research subjects. In some cases, it may be advisable to prepare plain language versions of the documents (see papunet.net/ plain language center). Templates for information can be found on the internet, e.g. FINPEDMED guidelines for children. In order to ensure the comprehensibility of the statement, the text should be read in advance by one or more layperson. Attention should also be paid to the visual appearance of the document.

A potential research subject is often addressed formally. However, the procedure varies according to the target group, and informal addressing is more and more common. Regardless of which method is chosen, the selected method of communication is followed throughout the informed consent form.

The informed consent should be dated, i.e. the date of the latest version, to distinguish between informed consents that may have been used at different timeframes. The informed consent used must be up-to-date, i.e. the latest version that has been evaluated by the Regional Medical Research Ethics Committee.

Guidelines on the Content of the Informed Consent

Name of the Research

Research - title of the research (short and clear, a longer subtitle is possible). The title of the research should be the same in all documents and should appear in all documents.

Invitation to Participation in the Research

A short and clear description of the purpose of the research.

An explanation of the reasons why the subject would be suitable for the research.

Voluntary Nature of Participation

In addition to the model text, the subject must be told what is part of normal medical care and what is part of this research. If the research is not related to the patient's care, the sentence concerning care of the patient and the patient-physician relationship must be deleted.

Research Conductor

Describe the researcher, the possible sponsor, the site-specific principal investigator in Finland and the research centre (e.g. Kuopio University Hospital.) Describe the contact person for the research.

Purpose of the Research

Explain the purpose of the research in a few sentences. The purpose of the research should not be stated as being a dissertation or similar study. In addition, an explanation of the selection and exclusion criteria and the estimated number of research subjects.

Flow of the Research

A brief description of the issues to be investigated, the duration of the research, the number and duration of the visits, the content of the visits and the measures to be taken. Description of randomization and the research subject possibility of being included in a control group, placebo treatment.

In addition to the actual measurements, the personal data to be collected from registers will be mentioned. If personal data will be collected, the registers used will be specified in the information sheet under 'Description of the Processing of Personal Data in the Study and the Rights of the Research Subject'.

For example: *“In addition, during the course of the survey, information about you will be collected from the data sources identified in more detail on page x.'. These will be used to determine XXX*."

If the health status of the research subject will be followed, this should be tell the subject, for example, as follows:

"Your health status will be followed for XXX days/months/years after the end of the research visits, but this will be based on the information collected from the above-mentioned data sources and therefore does not require your participation in any way."

The research subject should be informed if he/she will also be contacted by telephone. For example: “*In addition to the research visits, the research staff may contact you by telephone.”*

If the research involves genome analysis, the use of DNA samples must be clearly limited in accordance with the Ministry of Social Affairs and Health (STM) guidelines. For example: “*The*

sample is used to examine genetic characteristics that may be relevant to the determination of the characteristics of the research subject under investigation." Or: *"Genetic studies aim to identify hereditary factors associated with a disease and to determine their role in the pathogenesis of the disease."*

Potential Benefits of the Research

The potential benefits of the research are described realistically, without exaggerations that could be interpreted as an inducement to participate.

Research-related Potential Harms and Discomforts

Where appropriate, any additional measures that the research may entail compared to normal medical care (extra visits, etc.) and the effects of the research on life in general (special diet, exercise, sexual activity or other effects).

The main risks, inconveniences and discomforts, as well as the potential radiation risk, should be described in an understandable way, e.g. by comparing the radiation dose with natural background radiation. In addition, the precautions taken to deal with possible incidents should be described. If the subject is exposed to ionising radiation, the information sheet should describe in understandable language (1) the imaging study and the benefit to the study, (2) whether the imaging will cause additional radiation exposure, (3) the radiation dose and its explanation, and (4) the additional risk from the radiation. Subjects must be provided with a description of the benefits and potential health hazards of radiation exposure examinations and procedures in accordance with Section 113 of the Radiation Act (859/2018). Government Decree on ionising radiation (1034/2018) requires an individual exposure plan if the subject is expected to derive health benefits from the examination, procedure or treatment. Otherwise, a dose constraint must be used.

Processing of Personal Data and Confidentiality

See section 'Description of the Processing of Personal Data in the Study and the Rights of the Research Subject'.

Costs of the Research and Compensation for Participants

A statement on the reimbursement of travel expenses in accordance with the principles of Ministry of Social Affairs and Health Decree 82/2011 is attached. The research subject, his/her guardian, close relative, other close relative or legal representative may be reimbursed for the actual travel costs and loss of earnings incurred for participation in the research, as well as compensation for inconvenience.

Research Funding and Researchers' Conflicts of Interest

A statement of the research sponsor, any conflicts of interest and the researcher's employment status. For example, the research is funded by academic research funding (e.g. State Research Funding, foundation grant) or by a commercial company. The researcher subject should be

informed if the research team receives separate remuneration for the conduct of the research and of any conflicts of interest of the researchers and the funding body.

Insurance Coverage for Research Subjects

How research subjects are insured against personal injury and damage to property (patient insurance, health or medical liability insurance, insurance required for the study of equipment, etc., or insurance required for other types of study).

In the case of personal injury, compensation is sought from the Patient Insurance Centre's patient insurance. It covers personal injury in connection with health care and medical treatment under the terms of the Patient Insurance Act, under the conditions specified therein. Damage to property is not covered by patient insurance. The Patient Insurance Centre is responsible for the settlement of claims for damages caused to patients.

Communicating Research Results

Describes the information that will be provided to research subjects about their own results or about the study in general. In this context, it may be mentioned that this is XXX's doctoral thesis. If the research involves genomic research, the Ministry of Social Affairs and Health guidelines state as a general rule that the results of DNA research will not be disclosed to research subjects. The results are difficult to interpret and, in the light of current knowledge, are unlikely to be relevant to the health of the subject. Research subjects will be informed of any changes in the research that may affect their participation.

An explanation of whether the research subject will be informed of the results of the research, any incidental findings or other health information relevant to the research subject. If the research subject is not to be informed of the results, the reasons for this must be given.

End of the Research

Indicate the total duration of the study. Indication that the research may also be terminated by the investigator and the reasons for this. An explanation of the treatment at the end of the study.

Further Information

Any additional information related to the research.

Description of the Processing of Personal Data in the Research and the Rights of the Research Subject

Data Controller

Identify the data controller of the research. The data controller is the entity which, alone or jointly with others, determines the purposes and means of the processing of personal data. The data controller may be a natural or legal person, a public authority, an agency or any other body. A research team may also be a data controller.

The data controller determines "why the data are processed" and "how the personal data are processed?"

The data controller is responsible for, among other things.

- The technical and organizational measures for processing personal data
- What data are processed
- Who has access to the data
- For how long the data are processed

The Research will Process Data on

Details of the persons processing the data, both within the research and any disclosure of data to external parties. Also include public authorities, study monitors, sponsor, etc.

The Legal Basis for the Processing of Personal Data

In medical research, the processing of personal data may be based either on consent or on a legal ground for processing, depending on the research and the situation. It should be noted that, that consent as a ground for processing personal data is different from giving consent for participation on the research.

The choice of the legal basis for processing personal data is the responsibility of the data controller. The Regional Medical Research Ethics Committee of the Wellbeing Services County of North Savo recommends that the legal basis for processing personal data in medical research should be legal basis, the choice of which depends on the research type in question.

The processing of personal data in medical research is governed by the EU General Data Protection Regulation (EU) 2016/679, Articles 4 and 6 of the Data Protection Act (1050/2018) and Article 21a of the Medical Research Act (488/1999, Research Act).

In addition, the Act on Clinical Trials on Medicinal Products (Clinical Trials Act) provides for the grounds for processing personal data in clinical trials. The Regional Medical Research Ethics Committee will not deal with new clinical trials after the entry into force of the Medicines Research Act.

Medical Research

The processing of personal data in medical research is governed by the EU General Data Protection Regulation (EU) 2016/679, Sections 4 and 6 of the Data Protection Act (1050/2018) and Section 21a of the Medical Research Act (488/1999).

The processing of personal data for scientific research purposes in the public interest is governed by Articles 6(1)(e) and 9(2)(j) of the GDPR.

According to Article 21a(1) of the Medical Research Act, in the course of medical research, personal data may be processed pursuant to Article 6(1)(e) and Article 9(2)(i) of the GDPR if the processing is necessary for the purpose of protecting public health:

1) the purpose, performance, characteristics, effects and impact of the subject under investigation the quality, efficiency or safety of the product, or to determine or evaluate the quality, efficiency or safety of the product.
or
2) to ensure the safety of the subject or of other persons or to protect health, and the processing is proportionate to that objective.

The sponsor (data controller) should assess whether the research is of such a nature as to requires processing on the basis of a legal basis in order to protect public health.

According to Article 21a(2) of the Medical Research Act, in the course of medical research, personal data may be processed pursuant to Articles 6(1)(c) and 9(2)(i) of the GDPR if the processing is necessary:

1) to comply with the obligation to report an adverse event or effect or other safety-related reporting obligations;
2) to comply with any other obligation to report or account for the investigation or to preserve information or documents; or
3) to comply with an obligation to disclose information to a public authority.

The provisions of subsection 2 cover in particular the obligations under section 5(4) and (5) of the Research Act. These paragraphs provide for the suspension of the investigation and for the contact of the sponsor with the authorities.

However, if the research involves processing activities other than those covered by the above-mentioned Section 21a, the provisions of the EU Data Protection Regulation and the Data Protection Act apply. In addition, personal data may be processed for research purposes under the general data protection regulation, but at the same time subject to Section 21b(2), if the processing purpose falls within its scope.

Research on Medical Device

If the medical research is a device research (research on medical device or medical device performance research), the statutory processing grounds provided for in Section 21a of the Medical Research Act may be applied as processing grounds for personal data, regardless of the nature of the research project.

Section 6(2) of the Data Protection Act applies to the processing of personal data in the course of research.

Rights of the Research Subject

The basis of processing personal data also affects the rights of the research subject. If the processing basis is any other than described above (e.g. consent), the text describing the rights of the research subject must be revised to reflect the processing ground.

When choosing the right processing basis, it is worth paying attention to the research subject's rights, which vary according to the processing ground, e.g.

- If the legal basis for the processing of personal data of the research is "public interest of the research", follows that if the research subject withdraws his/her consent to participate in the research or discontinues his/her participation in the research, the personal data collected about the research subject may be used as a part of the research material.
- If the basis for the processing of research is "explicit consent" follows that if the subject withdraws his/her explicit consent his/her or discontinues to participate in the research (and there is no other basis for processing), the personal data collected until then from the subject must cease, i.e. it must be completely destroyed or made anonymous so that it no longer constitutes personal data.

The Research Will Collect Data from the Following Sources

Describe all the sources from which data is collected. The registers and the sources form which the data is to be collected from will be identified.

If the data collected in the survey will be saved in medical records, the sentence “The data collected in the survey will not be saved in your medical records” must be changed.

Transfer of Data Outside the EU/EEA

The transfer of personal data outside the EU/EEA is possible only if certain safeguards are met. If data are transferred outside the EU/EEA, the safeguards procedure for the transfer, which will be followed in the context of this research, must be described. The EU Commission may decide that a non-EU country or territory or a specific sector meets the same level of data protection requirements as those required of EU Member States. In the absence of a Commission decision, data may only be transferred if the third country has accepted and committed to the EU's standard data protection clauses and a separate agreement has concluded to this effect.

Restriction from the Rights of the Subjects

Where personal data are processed for scientific or historical research purposes, the rights of the research subject laid down in Articles 15, 16, 18 and 21 of the GDPR may be waived, where necessary. (Right of access, Right of rectification, Right to restriction of processing, Right to object). In the event that the research subject rights are restricted, the research subjects must be informed.

Any restriction from the research subject's rights laid down in Articles 15, 16, 18 and 21 of the GDPR requires an impact assessment in accordance with Article 35 of the GDPR. The impact assessment must be submitted in writing to the Data Protector Officer for information before the processing of data is started.

Retention Period of Data

The retention period of personal data is governed by legislation and good clinical research practice. Personal data will be destroyed when they are no longer needed for the research. However, it should be noted that in order to verify the accuracy of the results of the research, it is recommended that the data be kept for a predetermined period after the end of the research. In

the absence of specific legal provisions, research may be considered to be terminated when the last research subject has been subjected to all the measurements related to the research; in the case of observational studies, the research may be considered to be terminated when the predefined follow-up period has been completed.

Research duration means the period from the start of the research to the end of the data retention period. The period includes the collection and analysis of the data, the publication of the results and the storage of the data. At the end of the retention period, the data may be archived, but the legislation on archiving and the use of archived data must be taken into account.

The duration of the research should be planned and announced long enough to allow sufficient time for analysis and publication during the data retention period. However, the legislation on the processing of personal data requires that the duration of the retention of personal data should be minimized, so the declared duration of the research should not be unreasonably long.

It is the responsibility of the data controller to determine the retention periods for personal data or at least the criteria for determining the retention period if it is not possible to determine the retention periods precisely. The retention period of the personal records generated by the research should be specified and communicated to the research subjects.

The retention criteria below are taken from the legislation governing health sciences research. The retention period is therefore considered to start from the end of the study.

Medical device research (intervention). This research is a medical device research that involves intervention on the research subjects, i.e. testing the device by fitting it to the body (so-called "implementable device study"). The data and material from the study will be kept for 15 years.

Device study (non-interventional). This study is a medical device study, which does not involve intervention on the research subject (so-called "non-implemented study'). The retention period for the data and materials is 5 years, but 10 years from 2020 onwards.

Other research. Personal data will be destroyed no later than x years after the end of the research (see definition of end of study above). In order to verify the accuracy of the results of the research, it is recommended to keep the data for a predefined period after the end of the research.