**INFORMATION ON RESEARCH (*Date, version number*)**

(unofficial translation)

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

*(in italics is the text that needs to be deleted / edited from the final version, in yellow the parts that needs to be completed)*

# **Name of the Research**

XXX

# **Invitation to Participate in the Research**

You are invited to take part in research that investigates XXX. We have assessed that You are suitable for this research because XXX. This information describes the research and Your potential contribution to it.

After You have read this information and have familiarized Yourself on the research and asked questions, You will be asked if You are willing to participate in the research. If You wish participate in the research, You will be asked for Your written informed consent.

The Regional Medical Research Ethics Committee of Wellbeing Services County of North Savo has evaluated the research plan and given favorable opinion.

# **Voluntary Nature of Participation**

Participation in this research is voluntary. At any time during the research, You may decline to take part in the research, discontinue Your participation or withdraw Your consent without giving any reason. If You wish to withdraw Your participation or withdraw Your consent, please contact the principal researcher. Discontinuing or withdraw the research does not affect Your rights to the medical care You need. A representative of the research team will tell You about what constitutes Your normal medical care and what aspects are specific to this research. Participation in the research will not impact the medical care You receive.

# **Research Conductor**

The research is conducted by XXX, and the sponsor of the research is XXX. The site-specific principal investigator is XXX and the research center is XXX. *The foreign partners in the research are XXX.*

The contact person for the research is XXX.

# **Purpose of the Research**

The purpose of this research is XXX. The aim is also XXX. The information obtained from this research can be utilized for XXX.

In the research can be participate volunteers who are XXX. You are not a suitable participant if XXX. A representative of the research team will discuss with You to assess whether You are a suitable participant.

Approximately XXX research subjects in XXX countries will take part in the research. In Finland, approximately XXX research subjects will participate in the research.

# **Flow of the Research**

Your participation in the research will take about XXX days/week/year. The research will include XXX research visits XXX, lasting approximately XXX. During these visits, You will be subjected to the following measurements and/or tests: XXX, XXX and XXX. These will be used to determine XXX.

*You and Your potential representatives* will be informed of any changes of the research that may significantly affect Your participation in the research.

# **Potential Benefits of the Research**

It is possible that participating in this research may not provide direct benefits to You. However, the information provided by the research may help to understand XXX.

# **Research-related Potential Harms and Discomforts**

The expected harms of the intervention in this research are XXX, XXX and XXX. There may also be unanticipated harms associated with participation in the research. These may relate to XXX, XXX and XXX.

You participation in the research involves XXX additional research visits. In addition to the visits, the research will take approximately XXX hours of Your time. A representative of the research team will inform You about any other aspects related to this research that may affect Your daily life.

# **Processing of Personal Data and Confidentiality**

Your personal data is processed for *scientific research* purposes. The information collected about You and the results of the research will be handled confidentially as required by legislation. All parties and persons processing Your personal data are bound by confidentiality obligations. For a description of the processing of personal data in this research, see pages X-X of this information.

# **Costs of the Research and Compensation for Participants**

Research visits and research-related procedures are free of charge for You. You will not be compensated for participating in the research. *Any loss of earnings and travel expenses related to research visits may be reimbursed on the basis of receipts and other supporting documents.*

# **Research Funding and Researchers’ Conflict of Interest**

The research is funded by XXX. XXX *will pay the research center compensation for carrying out the research*. The investigator and other research staff *will/shall not be remunerated* separately for conducting the research. The researchers *have/have no conflict of interest to* XXX.

# **Insurance Coverage for Research Subjects**

In this research, the participants are insured under XXX.

If You suffer a personal injury as a result of *the research device or the procedure related to the research*, You can seek compensation from the research center's patient insurance.

# **Communicating Research Results**

This is scientific research, and the completion of the results may take several years. The

research findings will be published in scientific journals.

If any new information about the *research device or research procedure*, or information crucial for the continuation of the research, arises during the research, the research staff will immediately contact You to discuss whether You wish to continue participating in the research.

You will not be given individual feedback on the data collected about You during the research, as individual results may be difficult to interpret and are unlikely to be relevant to Your health.

If any abnormal findings are observed in the research results, the research staff will assess their significance and, if necessary, guide You to an appropriate follow-up medical care.

# **End of the Research**

The entire process from the commencement of the research to the publication of its results

is estimated to take approximately XXX, with the participation of the research subjects lasting around XXX.

Your participation may also have to be terminated prematurely by the investigator, principal investigator or research sponsor if it is deemed in the best interest of the research or Your well-being. If this happens, You will be contacted to discuss the steps to be taken to terminate the research.

*After the end of the research, Your normal medical care will continue as usual.*

# **Further Information**

If You have any questions related to the research, please ask XXX.

# **Contact information of Researchers**

**Principal Investigator**

*Title*

*Name*

*Unit / Clinic*

*Tel. (xxx) xxx xxxx*

*E-mail:*

**Researcher / Research Physician**

*Title*

*Name*

*Unit / Clinic*

*Tel. (xxx) xxx xxxx*

*E-mail:*

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

*(the text in italics is the text of the instructions, which should be removed / edited in the final version)*

The data controller of this research is XXX, who is responsible for the lawful processing of personal data in the research.

*(In this field the data controller is identified by its official name. The controller is the entity which, alone or jointly with others, determines the purposes and means of the processing of personal data. The controller may be a legal person or a natural person. Usually, the entity that determines the purposes of the processing of personal data is, for example, a wellbeing services county, a university or other similar entity.)*

Only the necessary personal data for the purpose of the research are stored in the research register. The collection of data is based on the research plan.

*(The Regional Medical Research Ethics Committee of the Wellbeing Services County of North Savo recommends that personal data will be processed on the basis of a statutory processing basis, which is selected on a research-by-research basis. When the research is medical research under the Medical Research Act, the legal basis for processing data may be, for example):*

In medical research, the processing of personal data is based on public interest and public health interest in accordance with Article 21a of the Act on Medical Research Act (984/2021) for processing operations essential to the performance of the research (Articles 6. 1.e and 9.2.i) and, in relation to safety reporting and other notifications to public authorities, compliance with a legal obligation and the public interest in public health (Articles 6.1.c and 9.2.i of the EU GDPR). In addition, the processing of personal data is based on scientific research purposes in the public interest (Articles 6.1.e and 9.2.j of the GDPR).

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

*(Where the research is a medical device research (clinical or performance research), the staturory basis for processing may be the above-described Section 21a of the Medical Research Act with the articles of the GDPR mentioned therein).*

In the research, Your personal data will be processed only by persons specifically appointed to the research team, whose tasks include the processing of Your personal data.

The identity of the research subjects is known only to the research staff, and they are all bound by confidentiality. All data collected in the research will be processed in a coded form after collection, which means that the names and personal social security numbers will be removed and replaced by a unique identifier code. Thereafter, the data on the research subjects cannot be identified without a code key, which will be kept by the principal investigator. The sponsor of the research, the member of the research team or third parties do not have access to the code key. The results of the research will be analyzed at the group level in coded form.

The research will collect Your personal data from the following sources: XXX, XXX and XXX.

In addition to the above, personal data concerning Your health status that are necessary for this research will also be collected from the following health care units and medical care records: XXX, XXX and XXX. The researchers will then be able to obtain the information they need by using Your personal social security number. The necessary authorizations from the authorities will be sought for the aggregation of Your data.

The collected data in the research will not be stored in Your medical records.

The research will *(transfer/not transfer)* Your personal data outside the EU and the European Economic Area (EEA) / Your data may be transferred in encrypted form to countries outside the EU and the European Economic Area (EEA), which do not all have the same level of data protection as the EU. In such cases, the sponsor of the research will ensure that the personal data are transferred using appropriate safeguards, which for the purposes of this research are XXX and XXX.

*Your data may also be processed by national and international supervisory authorities and by representatives and monitors of the research sponsor who are entitled to carry out audits. In addition, Your data may be disclosed to supervisory authorities. The research may also involve the procurement of laboratory and similar support services, in which case Your data may be processed by their providers.*

The retention period of Your personal data is regulated by law and good clinical research practice. XXX is responsible for the storage of Your personal data. This research is XXX and therefore the retention period is XXX years. After this period, the data will be destroyed.

If You discontinue the research, withdraw consent or if Your participation in the research is interrupted for any other reason, the data collected about You until that point may be used as part of the research data. This is necessary to ensure the safety of the research results and the safety of the research subjects.

You have the right to receive information about the processing of Your personal data and to request a restriction of the processing of Your personal data. You also have the right to inspect Your data and to request that it be corrected or completed (for example, if You discover an error, incompleteness, or inaccuracy). You also have the right to object to the processing of Your personal data.

However, these rights can be restricted in the context of scientific research. The law may require the data controller to retain research data for a certain period, regardless of the rights of the research subject. The law allows exceptions to the data subject's rights when necessary for ensuring the scientific research results and the safety of the subjects.

You can inquire at any time whether we are process personal data concerning You and the basis for the processing. You can also inquire about where we have obtained Your data and where Your samples and data have been disclosed. You have the right to receive this information free of charge and within a reasonable time (within one month of requesting the information). If Your request for information is very extensive or for some other justified reason particularly time-consuming to collect, the time limit for collection may be extended by up to of two (2) months. You will be notified of the extension and the reasons for it.

For data protection issues, we recommend that You contact the person in charge of the research or the data protection officer of the data controller *(if appointed*).

Contact details of the Principal Investigator:

XXX

Contact details of the Data Protection Officer of the data controller:

XXX

You have the right to file a complaint, especially with the supervisory authority based on the

location of Your habitual residence or workplace, if You believe that the processing of personal data violates the General Data Protection Regulation (EU) 2016/679. In Finland, the supervisory

authority is the Data Protection Ombudsman.

Office of the Data Protection Ombudsman:

Lintulahdenkuja 4, 00530 Helsinki, PL 800, 00521 Helsinki

Switchboard: 029 566 670

Email: (registry office): tietosuoja(at)om.fi

**INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

*(in italics is the text that needs to be deleted / edited from the final version*

**(Name of the Research)**

**(Research Site and Research Conductor)**

I (**the subject's name**) have been invited to participate in the above medical research for the purpose of XXX.

I have read and understood the information provided to me about the research. I have received adequate information about the research and the collection, processing, and disclosure of personal data in connection with the research. The contents of the information on research have also been explained to me verbally. I have had the opportunity to ask questions and have received adequate answers to all my questions about the research.

The explanations were provided by (**name of person**) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_ / \_\_/ 20 \_\_\_.

I have had sufficient time to consider my participation on the research. I have received adequate information about my rights, the purpose and conduct of the research, as well as the benefits and

risks of the research. I have not been pressured or coerced to participate in the research. I understand that my information will be treated confidentially and will not be disclosed to third parties.

I understand that my personal data will be treated confidentially and will not be disclosed to third parties *(if disclosed, please explain to whom the data collected during the research may be disclosed and how confidentiality of the data is protected. If the research involves international cooperation, a separate section on data disclosure should be added to the consent).*

I understand that my participation is voluntary. I have the right, at any time during the research and without giving any reason, to withdraw from the research. There will be no negative consequences for me and my status as a health care client will not be affected. I am aware that the personal data collected by the time of my withdrawal will be used as part of the research data.

**By signing this document, I confirm that I am participating in the research described in this document and that I voluntarily agree to be research subject. I am aware that my personal data may also be processed in the context of an inspection by a foreign authority and quality assurance activities carried out by a representative of the sponsor.**

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Person’s name Person’s date of birth Person’s address

*(or social security number)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Patients’ representatives name Date Signature

*(if necessary*)

**Consent received**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Research’s /Nurse's Name Date Signature

(Recipient of the consent form)

The original signed informed consent form, along with a copy of the research information,

will be kept in the researcher’s archive. The research information and a copy of the signed

consent form will be provided to the participant.

*(If consent is given electronically (e.g. signed on an electronic platform accessed via strong authentication), a consent signed jointly by the research subject and the research team member is not required. Where consent is given remotely by electronic means, the research subject must verbally confirm that the consent is his/her own before the intervention.)*