***Clinical trial information leaflet and consent***

## General

## You must provide sufficient information on the rights of clinical trial subjects, the purpose and nature of the trial, the methodologies used as well as the potential risks and adverse effects involved to allow the prospective participants to provide informed consent. The information must be provided in a format that allows the participant to decide whether or not to enter the study based on a clear knowledge of all relevant factors that may influence their decision-making process.

## The document provided to the prospective participants must comprise an information sheet with details of the research/study as well as a consent form. Together, they form an indivisible whole, the written material based on which informed consent is provided. If required, information must also be made available to the participants verbally.

The information provided to participants must be relevant, short and succinct. The length should not exceed five sheets of A4 and should be shorter wherever possible. It should be written using layman’s terms, in plain, everyday language. If you need to use technical terms or so-called jargon, for reasons of clarity, for example, please provide an explanation when this type of terminology first appears in the text. Please remember to use a font size that is easily readable.

You should avoid using language that may come across as forceful, patronising or persuasive.

If you are seeking consent from a clinical trial participant’s representative, please adjust your documents accordingly. Information leaflets and consent documents aimed at children or adults with reduced capacity must be specifically tailored to their needs. Please ensure that you use language that your target audience can easily understand. Depending on the circumstances, it may be appropriate to create a simplified version of the documents.

Some Finnish documents, continue to use the formal address of ”te” (you). However, the use of the informal ”sinä” (you) is becoming more prevalent.

You can create a separate document to provide more detailed information or instructions regarding any procedures performed as part of the study.

We recommend that you invite one or more lay people to proofread your text prior to publication to make sure that it is easily understood. It is also important to consider the visual appearance of your document.

In the document template, the italicised text in brackets is intended as instructions for the authors. The template also contains passages where further support is provided in the form of sample sentences and optional content.

The original signed document should be retained by the doctor conducting the research and a copy provided to the participant.

Written consent can also be provided electronically. If you intend to use an online system for obtaining consent, please provide a description of the method and your reasons for opting for this alternative in your application to the committee.

## CLINICAL TRIAL INFORMATION LEAFLET

(*Addressed to the prospective research subject*)

## Brief title of the study

(*A trial is uniquely identified by a code, EudraCT-number and Finnish name. Please make sure that the title used here is concise. If you would like to expand on the title in more detail, please use a subtitle*.)

## Request to participate

You are invited to take part in a clinical trial investigating (*short and concise description of the purpose of the trial*). We think you would be a suitable candidate because (*description for why the subject would be suitable, in the event of a clear cause is found,* *cf. the research in healthy* *volunteers).* This information leaflet explains what the clinical trial will involve and your role in it if you decide to take part.

## Participation in clinical trials is voluntary

It is up to you whether you decide to take part in this clinical trial. You can choose not to take part or change your mind or withdraw from the clinical trial at any time without telling us why. If you do decide to refuse or withdraw, it will in no way affect your right to continue to receive the treatment you need.

You do not need to volunteer for this clinical trial to receive medical treatment and care. Your doctor will discuss your treatment options in more detail (*applies only to studies in patients*).

Please take time to read the following information carefully. If you have any questions, contact the study doctor or another member of staff involved in conducting the study for more information. Their contact details are provided at the end of this document. If you decide to take part in the clinical trial, we will ask you to sign the consent form on the last page.

## Details of the organisation and individuals responsible for carrying out the clinical trial

This clinical trial will be/is being carried out by (*name of principal investigator (PI), same as the person in charge of the trial in Finland; trial site and site PI; sponsor; clinical research organisation*). X *(note that responsibility for this role may be shared)* acts as the data controller for this study and is responsible for ensuring that your personal information is handled in accordance with the law at all times.

## Background and purpose of the trial

In this trial, we will be looking at whether a new medicine is effective and safe to use in the treatment/prevention/etc. of (*medical condition, e.g. type 2 diabetes, epilepsy, hypertension etc*.). We are also trying to find out (*any other end points and objectives*).

The medicine (*please include name*) is a new preparation, which works by (*e.g. increasing insulin production in the pancreas and lowering your blood sugar, or equiv.*) or is already being used to treat X but its efficacy and tolerance have not previously been investigated in the treatment of X (*patient cohort*). We consider that investigating X (*name of medicine*) is important because (*short explanation*).

(*In case of placebo-controlled trial, please explain the concept and your reasons for choosing this method.*)

So far, X (*number*) of patients or research participants have been given this medicine.

We are looking for volunteers aged X, (*e.g. with coronary artery disease but no other cardiac impairment*) etc.

Some X volunteers from X countries will be taking part in the trial. Some X Finnish volunteers are involved.

(*Please describe in this contest, if there are any other objectives for this trial, e.g. if the data collected in this trial is intended to be used in future research to investigate other medicines and diseases. To examine the safety of the medicines may require the comparison of the different research data. The relevant information related to these other purposes shall also be taken into account in the section “Confidentiality and data protection”*.)

## Trial methodology and procedures (please include a concise overview of trial methodology and procedures in lay terminology)

This clinical trial will take place over X days/weeks/years.

You will be asked to attend X appointments. The research staff may also contact you by telephone. We will also continue to monitor you for X days/months/years after your appointments have ended (*it is also important to explain, how to the monitoring is carried out*).

The clinical trial will be conducted (*please provide details of trial methodology and arrangements, screening/eligibility, monitoring, controls used, placebos used, randomisation, blinding, particularly in the case of randomised placebo-controlled trials, please explain that the patient may not receive any effective treatment during the trial and the likelihood of that happening as well as knowledge that neither researcher knows which medicine will be given to the clinical trial subject*).

During the trial, X blood samples will be taken from you. We will also carry out X medical examinations etc. In addition, we will be performing X procedures (*coronary angiogram, ECG or similar*) that will be used to… (*please ensure that you have fully explained any additional procedures or visits that will be required and any medicines they will not be able to take during the trial period*).

This trial will include genetic analysis, which purpose is to (*description for genetic research and the use of samples; pharmacogenetics, pharmacogenomics (or equiv.)*). Genetic research will be conducted to study the role of the genome in drug response, the efficacy and safety of the drug (or equiv.). (*It is recommended that the possible genetic test is handled and presented as part of the primary information leaflet.*)

During the trial period, we ask that you pay particular attention to the following (*influence on everyday life, diet, exercise etc.*).

All fertile age potential must use effective contraception for the duration of this trial (*or equiv.*). You will be automatically excluded from this study if you are pregnant, plan to become pregnant or breastfeeding as the effects of this drug on the foetus are unknown. If necessary, the trial doctor will discuss the suitable contraceptive methods with you.

## Potential benefits of participation

It is possible that there will be no direct benefit to you when taking part in this study. However, this trial may help us to understand whether this medicine/procedure/etc. is safe and effective. We may also find out useful new information about the medical condition we are investigating. (*Please also ensure to explain to the participant whether they will be informed of the results, including any incidental findings or other health-related information relevant to the participant. If the intention is to withhold this information, the procedure must be explained and reasoned to the participant).*

## Risks of participation

The most common known or presumed adverse effects are (*please ensure that you explain to the participants all known risks, adverse effects and any inconvenience or discomfort involved as well as their probability, all serious adverse effects must be explained apart from the minor effects*).

The trial doctor can discuss any other adverse effects with you.

There may be unforeseen risks associated with participation of the trial and /or medicine used in it. If, during the course of this trial, we receive any relevant new information about this preparation, the trial doctor will contact you immediately and discuss whether you wish to continue to take part in the study.

(*The same requirements applies for any reference drugs used in trial.*)

## Confidentiality and data protection

Your identity and other identifiable information will only be known to the clinical trial personnel. All staff involved in the trial are legally required to maintain complete confidentiality at all times. All information and samples collected from you during the trial will be identified by a unique trial code, which ensures that you cannot be personally identified in any publication, report or presentation of results in the future.

Only personal information that is absolutely needed for the trial will be entered in the trial register. Your name and personal identity code will never be distributed to the sponsor of the trial (*exception investigator-driven research*). In the trial results and other documents, you will be referred to by your trial code only. The register will be stored at (location) until (*the trial has ended/ legally required etc*.). A so-called description of file (“*rekisteriseloste” in Finnish*) will be drawn up of your personal data file as required in the Finnish Personal Data Act, and you can request to view it at any time.

With your authorisation, we can request information related to the state of your health and relevant to the study held by other healthcare providers and in other healthcare registers *(registers and the data to be collected shall be identified; this information can be given later when applicable).* The study doctor can request the information using your personal identity code.

The Finnish Medicines Agency (Fimea) has the powers to ensure that the trial has been carried out and all trial data has been obtained appropriately. International medicines agencies and representatives of the sponsor can also carry out inspections. This is done by comparing the trial information to original medical records and health information. During any inspections, all information will be accessed under the supervision and at the responsibility of the trial doctor. The data may also be used to apply for a marketing authorisation for the product. Your personal information will be handled with the utmost confidentiality at all times.

Coded information related to you may be transferred to non-EU countries (*please specify which*), where the data protection arrangements may be different to those in place in Finland and /or other European countries.

Information relating to you may also be disclosed to (*another researcher, another sponsor following a corporate acquisition etc.*). However, all parties will continue to be bound by their obligations of confidentiality. (*It is possible to state here that data will only be used for scientific purposes and will not be disclosed to any third parties such as insurance companies.*)

(*If the results of the trial are intended to be shared through international public databases, please provide details of which database are in question, i.e. dbGaP or equivalent. Also many scientific publications require to make the data available for independent scientific review.*)

If you stop participating in the study for whatever reason or you decide to withdraw your consent, the information gathered until that point will be included in the study and used to evaluate the safety of the medicine used. This is essential to validate the results and to assess the reliability and robustness of the research data.

## Expenses and statement of financial interests

You will not be charged for the medicine or any of the procedures involved. Any loss of earnings and travel costs arising from attending the appointments will be reimbursed on the original receipts.

(*If healthy volunteers are to be paid compensation for discomfort please state this clearly and provide the rationale for doing so.*)

X will provide the funding for the clinical trial. The trial site involved in the trial will receive financial remuneration from X. The trial doctor and the research staff will be paid (or will not be paid) compensation for the conclusion of the study (*or equiv*.). (*Any possible financial liability of the research personnel as well as any other financial interests, including scientific discoveries, patent applications, business start-ups, shall be explained here.*)

## Insurance for trial participants

If you are harmed by taking part in this clinical trial, either because of the medicine used or procedures performed, you may seek compensation.

If you suffer an injury related to the trial medicine, you can make a claim for compensation through the Finnish Cooperative for the Indemnification of Medicine-Related Injuries. The pharmaceutical injuries insurance will pay compensation for any unexpected adverse effects you have suffered as a result of the trial medicine in accordance with the policies set out in its terms and conditions. (*Please adjust accordingly if the medicine is not insured with the Finnish Cooperative for the Indemnification of Medicine-Related Injuries*).

You can seek compensation for any other injuries through so-called patient insurance. Patient insurance provides compensation for injuries sustained in connection with healthcare in accordance with the Patient Injuries Act. The Finnish Patient Insurance Centre is responsible for processing compensation claims.

## The conclusion of the clinical trial

The trial doctor will discuss your treatment needs after the trial comes to an end *(only treatment-related trials).* You will get to know what medicine you received during the investigation. You will/ will not be informed of the trial results (*the reasoning must be given in case of withholding the results*).

The study doctor or trial sponsor may need to withdraw you from the study prematurely. If that is necessary, the possible implications will be discussed with you.

## Further information

If you have any questions about the trial, please contact the trial doctor or other personnel conducting the trial.

They are able to talk to you about any issue that may be concerning you, including possible side effects or unusual symptoms you may have experienced.

Contact details:

***CONSENT TO PARTICIPATE IN THE CLINICAL TRIAL***

I have been asked to participate in a clinical trial (*unambiguous identification name, code or EudraCT-number of the trial*)*.*

I have read the clarification above and I have received an adequate information regarding the trial, also the collection, processing and disclosure of data in conjunction with it. The content of the trial has been explained to me verbally and I have received a sufficient answer to all my questions relating to the trial. The information was given by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*name of the person*). I have had sufficient time to consider my participation in the trial.

I understand that my participation in this trial is voluntary. I have the right at any time to interrupt the participation or to withdraw my consent without having to give any reason. My refusal to participate or withdrawal does not affect my subsequent care or my patient status. I am aware that information collected before the withdrawal of the consent will be used as part of the trial master file and for the safety assessment of the drug.

**With my signature I verify my participation in this trial and consent to being a voluntary trial subject. I consent to gathering information about me\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*location and/or register, where data is gathered*). I consent to** **my personal information being disclosed to international medical authorities for inspections purposes, and to representatives of the study sponsor for quality assurance purposes.**

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

*Signature Date*

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

*Print name Date of birth or personal identity code*

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

*Address*

***Confirmation of receipt***

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

*Signature of the person receiving the consent Date*

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

*Print name*

# The original signed consent and a copy of the information leaflet will remain in the files of the doctor conducting the research. The information leaflet and a copy of the consent will be given to the trial subject.