**Information leaflet on genetic/pharmacogenetic research and sample consent form**

**General**

Many clinical trials encompass a genetic or pharmacogenetic research component *(or equivalent)*. This component is often designed to gain a better understanding of the relevant medical condition and/or the efficacy or other characteristic of the drug used to treat it.

The National Committee on Medical Research Ethics (TUKIJA) recommends that a description of the genetic/pharmacogenetic component is included in the participant information sheet for the main clinical trial. If the intention is to conduct the genetic/pharmacogenetic research as a separate and additional study, the sponsor can use the sample information sheet and consent form included below. The text and, where relevant, the headings must clearly refer to a so-called additional trial.

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 four 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.
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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.

(ADDITIONAL) GENETIC/PHARMACOGENETIC STUDY INFORMATION LEAFLET
(Addressed to the prospective clinical trial participant)

Full title of your study
(Please make sure that the title is short, clear and precise, e.g. genetic/pharmacogenetic research relating to the X clinical trial.)

Request to participate
You have been given this information leaflet because you are considering taking part in a clinical trial investigating whether a new drug will be safe and effective in the treatment of X (medical condition such as Type 2 Diabetes, epilepsy or hypertension, etc.). If you decide to participate, we would like to ask you to also consider participating in (genetic research, pharmacogenetic study, genetic screening or similar), which we will be conducting as part of the X clinical trial. This information leaflet explains what this study 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 study 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 can also choose to participate in the X clinical trial but decline to take part in this genetic research/pharmacogenetic study.

Please take your time to read this information carefully. If there is anything you are not sure about or if you have any questions, you can contact the 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 study, we will ask you to sign the consent form on the last page.
Details of the organisation and individuals responsible for carrying out the study

This study will be/is being carried out by (please include name of principal investigator (PI), same as the person in charge of the investigation in Finland), clinical 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 this study

Our genes are implicated in the onset and progression of many diseases. We also know that the way medicines are absorbed, distributed, metabolised and excreted by the body and/or the effect that they have can vary between people. One reason for this variation is that all human beings are genetically unique.

This study has been set up to try and identify the type of genetic variations that may affect the safety or efficacy of X (insert name of medicine or equivalent).

We would like to use the samples and information collected as part of this study in future research to investigate other medicines and diseases. For this reason, we are asking for your consent for them to be stored at our company’s/clinical research organisation’s sample collection for possible later use (or similar). (Under all circumstances, you must be able to provide a clear explanation and rationale for the future use of the samples.) The transfer of samples to a biobank is subject to a separate consent process and instructions (for further information, please visit http://www.bbmri.fi).

Study methodologies and procedures (please include a concise description of trial methodologies and procedures using lay terminology)

As part of this study, we will ask all participants to provide a blood sample. We will require a sample of X ml. This sample can be taken at the same time with other samples and will not involve an additional visit or procedure. The additional sample will be taken during (a visit, a separate visit or similar).

The study will be conducted (please provide details of how the sample will be handled, how they are coded/anonymised, what information will be included in the sample, how they will be transferred between sites, where the genetic analysis will be carried out, how the results and samples will be stored and disposed of, etc.)

The potential risks and benefits of participation

This type of study will not usually offer direct benefits to you personally. However, it may help us to understand whether this medicine/drug/treatment/etc. is potentially safe and/or effective and whether our individual genetic characteristics influence how safe and effective it is (or equivalent). In future, this information may help doctors identify the patients who will benefit most from the treatment. We may also gain useful new information about the medical condition we are investigating.

(If you do not require the participant to provide a separate blood sample for the purposes of your study and/or a small volume of blood is required, it is not expected that the procedure will result in physical adverse effects or discomfort to the participants. In the event that physical adverse effects or discomfort are possible, you must explain this in the appropriate level of detail.)
(Please also ensure that you 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 it is your intention to withhold this information, you will need to explain your rationale for this decision.)

Confidentiality and data protection

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

Only personal information that is absolutely needed for the trial will be entered in the trial register. Your name, contact details and personal identity code will always be stored separately from other study data. In the results and other documents, you will be referred to by your trial code only. The register will store at (location) until (the trial has ended/legally required for the purposes of marketing authorisation or other legislation 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 other information related to your health and relevant to the study held by other healthcare providers and/or in other regional/national healthcare registers (please provide as much detail as possible at this stage on the registers and type of information you are referring to). The study doctor can request the information using your personal identity code. The Finnish Medicines Agency (FIMEA), as the competent Finnish authority, has the powers to ensure that the parts of the study relevant to a clinical trial have been carried out in the appropriate manner. International medicines agencies and the clinical trial sponsor’s representatives are also entitled to carry out inspections. Your personal information will be handled with the utmost confidentiality at all times.

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. (At this point you should explain in practical terms how participation is discontinued, what will happen to the samples provided if the participant decides to withdraw from the study, what else the participant should take into consideration, etc.)

Coded information relating 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.

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

Information relating to you may 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.)
Expenses and statement of financial interests

(If the trial subjects will incur travel expenses as a result of their participation, please set out what expenses they can re-claim here).

X will provide the funding for this study. The site where the study is conducted, the doctor conducting the study and all other members of staff will be paid by X. (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 study participants

If you are harmed by taking part in this study, you can seek compensation through patient insurance. (If the sponsor has additional insurance in place, please declare it here.)

Further information

If you have any questions about the study, please contact the doctor conducting the study or another member of the team.

Contact details:

CONSENT TO PARTICIPATE IN THE GENETIC/PHARMACOGENETIC STUDY

I have been asked to participate in a genetic or pharmacogenetic study conducted as part of a clinical trial (please provide title, code or EudraCT number).

I have reviewed the description above and I have received adequate information regarding the research, also the collection, processing and disclosure of data in conjunction with it. The content of the study has been explained to me verbally and I have received a sufficient answer to my questions relating to the research. The information was given by _____ (please insert name). I have had sufficient time to consider my participation in the research.

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.

With my signature I verify my participation in this trial and consent to being a voluntary research subject. I consent to my personal information being disclosed to international medical authorities for inspection purposes and to representatives of the study sponsor for quality assurance purposes.
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Template 2

________________________  __________________________
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.