Clinical trial information leaflet

General

It is recommended that you address the research subjects directly. Please avoid the passive tense.

The information leaflet should not exceed five sheets of A4 and should be written in layman’s terms using plain language. Please also remember to use the appropriate font size for ease of reading.

If you are seeking consent from a research subject’s representative, please adjust the text accordingly. Information leaflets aimed at vulnerable subjects such as children or adults with incapacity must always be specifically tailored with the needs of the target group in mind. Please ensure that you use language they can understand.

A separate information leaflet can be made to provide further information, instruction or guidance on any procedures performed as part of the trial.

CLINICAL TRIAL INFORMATION LEAFLET
(Addressed to the prospective research subject)

Brief title of project
(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.)

Invitation 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). This information leaflet explains what the clinical trial will involve and your role in it.

Participation in clinical trials is voluntary
It is up to you whether you want to take part in this clinical trial. You can choose not to take part and even if you do decide to participate, you can change your mind at any time without reasoning.

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.

The study doctor or trial sponsor may need to withdraw you from the study. If that is necessary, they will discuss any further measures with you.
Please take time to read the following information carefully. If you have any questions, contact your study doctor or another member of staff involved with the project, who can discuss it with you in more detail. If you decide to take part in the clinical trial, we will ask you to sign the attached consent form.

**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, trial site and site principal investigator, sponsor and clinical research organisation). (X) acts as the data controller for this study and is responsible for ensuring that your personal information remains confidential at all times, in accordance with data protection legislation.

(Any links between the researchers and the sponsor/clinical research organisation should be stated here.)

**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 of (medical condition, eg. type 2 diabetes, epilepsy, hypertension etc.). We are also trying to find out (any other research aims).

The medicine (please include name) is a new preparation, which works by (eg. 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:

(If you are seeking volunteers for a placebo-controlled trial, please explain the concept and your reasons for choosing this method.)

So far, (X) (number) of patients have been prescribed 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.

(If the trial will be used to secure a marketing authorisation for the product, you may wish to state that here.)

**Trial methodology and procedures (Please include a concise overview of trial methodology and procedures in plain language)**

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.
The clinical trial will be (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).

During the trial, we will take (X) blood samples 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).

During the trial period, we ask that you pay particular attention to the following: (diet, exercise etc.).

All fertile women must use effective contraception for the duration of this trial. If necessary, the trial doctor will discuss your method of contraception with you. 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.

All men must use effective contraception for the duration of this trial (or equiv.).

**Benefits of participation**

It is possible that there will be no direct benefit to you from 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 condition we are investigating. Medical examinations and laboratory tests will be done during the trial to monitor your health. You will be informed of the results.

**Risks of participation**

The most common known or presumed adverse effects are (please ensure that you explain to the volunteers all known risks, adverse effects and any inconvenience or discomfort involved as well as their probability, volunteers must be advised of all serious adverse effects in advance).

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

There may be unforeseen risks associated with the trial medicine. 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.

(Please bear in mind that you will need to provide the same details for any reference drug? you may be using.)

**Confidentiality and data protection**

Your identity and other identifiable information will only be known to the clinical trial staff. 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 recorded. In the trial 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 etc.). A so-called description of file (rekisteriseloste) will be drawn up of your personal data file as required under the Section 10 of the Finnish Personal Data Act, which you can view 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. The study doctor can request the information using your personal identity code. You have the right to view your own personal data at any time and, if necessary, ask for it to be corrected.

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. If you consent to it, international medicines agencies and representatives of the sponsor can also carry out inspections. During any inspections, all information will be accessed under the supervision and at the responsibility of the trial doctor. Your personal information will be handled with the utmost confidentiality at all times.

If you withdraw from the trial for any reason, the information gathered until then will be used as part of the trial and to assess the safety of the medicine used.

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.

**Costs and reimbursements**

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 basis of written receipts.

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

(Xxx) will provide the funding for the clinical trial. All staff involved in the trial will receive financial remuneration from (Xxx).

**Insurance for trial volunteers**

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 relating 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. You will/will not be informed of the trial results (blinding/test results etc.).

(Genetic test results may be difficult to interpret or, based on current knowledge, it may be difficult to assess their significance and impact on the subject’s health. If your trial involves genetic testing, it may be advisable not to divulge the results to the subject.)

**Further information**

If you have any questions about the trial, please contact the trial doctor or another member of staff. They will be pleased to talk to you about any issue that may be concerning you, including any side effects or unusual symptoms you may have experienced.

Contact details:

**Consent forms**

Drafted by Pharma Industry Finland, Office of the Data Protection Ombudsman, National Committee on Medical Research Ethics

http://www.tukija.fi/fi/julkaisut/lomakkeet (in Finnish)
http://www.tukija.fi/sv/publikationer/blanketter_och_dokumentmallar (in Swedish)

FINPEDMED sample documents for parents and children for paediatric clinical trials