Information Sheet and Consent Form template
Guideline (clinical trials on medicinal products under EU Regulation 536/2014)
T/447/2026
25.6.2026 (translation on 25th June 2026)

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM TEMPLATE

1.1 General

In order for a person considering participating in a clinical trial to be able to give their informed consent, they must be provided with a sufficient explanation of the rights of the research participant, the purpose and nature of the trial, the methods and procedures used, the processing of personal data and any risks and inconveniences. This explanation must be provided in such a way that the person is able to decide on whether to participate in the trial, being aware of relevant circumstances in the trial that may affect their decision. The information provided must be relevant for participating in the trial and written so as to be understandable by a layperson. The information should also be concise in form.

The Information Sheet and a Consent Form together form the **written documentation of informed consent**. Information must also be provided in person as needed, and potential participants must be given the opportunity to ask questions.

The Information Sheet must be **brief, concise and to the point** (about 5–8 pages in length, in any case no more than 10 pages). The document must focus on the salient facts and must be written in clear and understandable language. If any foreign terms or professional jargon must be used, they must be defined and explained in common language on their first occurrence in the text. Font size and document layout may also affect how easy the document is to understand.

- The limitation on the number of pages applies on a case-by-case basis; in a complicated research scenario, the Trial Information Sheet and Consent Form can justifiably somewhat exceed the above recommendation of length. Features affecting the readability and length of the text include avoiding repeated addressing of the reader, avoiding giving detailed instructions or describing procedures in detail, and avoiding repetition.

The Information Sheet should not contain any text that comes across as a command, an exhortation or an enticement. The text should also not be based on the assumption that the person will agree (e.g. “Once you have signed the Consent Form…”).

The potential participant should generally be addressed formally. However, depending on the target group, a more informal approach is also possible. The pronoun *you* (in Finnish, *te/sinä*) may be written with a capital or lowercase first letter. The chosen form of address must be used consistently in all materials given to research subjects.

Care should be taken to ensure that the units of measurement and time used in the Information Sheet are consistent and comparable (as examples, using days, weeks, months and years interchangeably may be confusing; and tablespoons are not a common unit of measurement in a Finnish context). When translating an Information Sheet from a foreign language, ensure that the phrasing and information are consistent with the Finnish operating environment.

An Information Sheet issued to research participants is a document on the basis of which potential participants will make the decision whether to join the trial. Detailed explanations of or instructions for procedures to be carried out during the trial may be issued in a separate instruction document. This instruction document must also be brief, to the point and understandable. The Trial Information Sheet must not contain any instructions to research subjects. Any duplication of information between the Information Sheet and the separate instruction document must be eliminated. Basically, the Trial Information Sheet should not contain any instructions at all (such as a detailed guide on how to use the investigational medicinal product).

- The potential participant will decide whether to join the trial based on the Information Sheet, the Consent Form and any appendices provided. Once a person has decided to join the trial, they may be given further information. There is no legislative requirement for entering such instructions in the CTIS. The above should, however, not be interpreted to mean that the Information Sheet must never contain any instructions. For instance, any dietary restrictions must be specified in the Information Sheet so that the potential participant will know what participating in the trial will require. Similarly, details such as if the investigational medicinal product is to be administered by injection are relevant and should be included in the Information Sheet.

In order to ensure that the explanation is understandable, it should be given to one or more laypersons and to the research staff to read before publication. The visual appearance of the document is important.

- The views of the patient group whom the study concerns should also be consulted in preparing the Information Sheet.

In the attached template, text that is in brackets *in italics* is intended as instructions to authors. The template also contains sections with examples or options for the author to choose from. Bullet points are used to list additional notes and justifications for why particular things are presented and written in a particular way.

The original signed document is to remain in the archive of the research physician, while a paper copy or electronic copy is to be given to the research participant or their representative.

1.2 Vulnerable groups

The Information Sheet template is written with the assumption that the potential participant can decide for themselves whether to participate in the trial. If consent is instead sought from a research participant's representative, then the text of the template must be modified accordingly. A separate Information Sheet and Consent Form must be prepared for research participants' representatives. When requesting consent, the provisions in sections 13–14 of the Act on Clinical Trials (983/2021) complementing the EU Regulation on clinical trials on medicinal products (536/2014) must be complied with. Information Sheets must be written in a style that can be well understood by the target group. In some cases it may be recommendable to author separate easy-language versions of the documents. More information on easy language can be found on Papunet https://papunet.net/ (in Finnish) and on the Selkokeskus website https://selkokeskus.fi/in-english/.

- The EU Regulation on clinical trials uses the term "legally designated representative". Under section 13(2) of the Act on Clinical Trials, if there is no legally designated representative, then informed consent may be given by a family member or other close person.

- If research participants are being recruited by specific group (e.g. on the basis of their age or cognitive abilities), then a separate Information Sheet must be authored for each such group.

For children or for adults with impaired self-determination capacity, separate documents must be prepared, taking into account factors such as the developmental level of children of various ages when considering whether the documents are readable and understandable. The length of the documents must also be considered. In trials involving children and adolescents, information must be provided both to legally designated representatives (e.g. guardians) and to the research participants themselves (children, adolescents) in order for the latter to participate in the consent process. In studies involving children, age groups may be applied on a case-by-case basis: children under school age, teenagers, etc. Information Sheet templates can be found online and can be used as applicable, adapted as per the research plan (e.g. FINPEDMED guidelines for children). In Finland, an adolescent aged 15 or above may give their informed consent independently if there is a scientifically justified reason to assume that participating in the clinical pharmaceutical trial in question may yield immediate benefits to the adolescent in question that outweigh its risks or inconveniences. In such a case, the guardian of the research participant must be informed of the decision of such an adolescent to participate in the trial.

- Matters having to do with contraception and pregnancy should basically never be included in an Information Sheet intended for children under the age of 12.

1.3 Data protection

The Information Sheet must include an explanation of the grounds for processing personal data as per the EU General Data Protection Regulation (GDPR, 2016/679). As per section 33 of the Finnish Act on Clinical Trials, Articles 6(1)c, 6(1)e and 9(2)i of the GDPR may be cited as grounds for processing personal data. The controller is responsible for determining the grounds for processing. Research participants must be informed of the controller and of the processing of personal data (Articles 12–14 of the GDPR) in such a way that they may, on the basis of this and other information concerning the trial, make a decision on whether to participate in the trial. Some of the this information may be issued in an appendix to the Information Sheet or in the privacy statement.

1.4 Radiation risks

If radiation administered in the trial causes no greater exposure to the research participant than conventional therapy, this must be stated in the Information Sheet. If, however, the research participant will be exposed to ionising radiation exceeding conventional therapy in the course of the trial, it must be explained in the Information Sheet in understandable language (1) what the imaging examination in question is and what its benefit for the study is; (2) what the radiation dose is and its explanation; and (3) the risk of death by cancer resulting from the radiation. The risk level must be given specifically for each imaging examination (as instructed in the guideline mentioned below). If the trial involves several imaging examinations, the Information Sheet must indicate how often they are performed and what the total radiation dose will be. Under section 113 of the Radiation Act (859/2018), a description of any examinations, procedures or treatments exposing the participant to radiation must be given, detailing their benefits and any possible health detriments. Furthermore, as per section 9 of the Government Decree on Ionising Radiation (1034/2018), the radiation exposure of a research participant taking part in medical research must be planned individually if the health of the research participant is expected to gain medical benefit from the examination, procedure or treatment. Otherwise, a dose constraint must be applied. It is recommended to consult the *Guideline for medical research exposing research subjects*

to ionising radiation (9 Feb 2022, in Finnish). The guideline can be found on the Tukija website: https://tukija.fi/laaketutkimusasetuksen-mukaiset-hakemukset.

1.5 Decentralised trials

Jos tutkimukseen sisältyy hajautetun tutkimuksen *(decentralized clinical trial, DCT)* elementtejä, jotka voivat vaikuttaa tutkimuksen toteuttamiseen (kuten etävastaanotot, sähköinen suostumusmenettely), tulee asia soveltuvin osin huomioida myös tutkimuksen tiedotteessa.

1.6 Re-consent

In a situation where a re-consent is requested from a research participant already participating in a clinical trial (e.g. as a result of an update of safety information), the changes and additions must be clearly indicated in the text. In this case, a summary of changes can be added to the beginning of the release. See more details *Guideline for good clinical practice* (ICH E6 [R3], 2.8.2).

INFORMATION SHEET ON A CLINICAL TRIAL ON MEDICINAL PRODUCT(S)

- The title of the Information Sheet must clearly state that it concerns a clinical trial on medicinal product(s) (and not e.g. “Information sheet on a study”).

Title of the trial

(The trial must be unambiguously identified using a code and a title in Finnish. The title must be concise and clear. If the trial has a longer, official title, this may be included as a subheading.)

- If the trial has a code, the code must be given.

EU trial number:

Request to participate in the trial

You are requested to participate in a clinical trial on medicinal product whose purpose is to investigate (*concise and understandable description of the purpose of the study*). We have estimated that you would be suitable for this trial because (*explanation of why the person is suitable for the trial, assuming that there is a clearly defined reason*). This Information Sheet explains what the trial is and what your part in it would be.

- It must be specified that the study is a clinical trial on medicinal product(s), not just in the title but at the beginning of the body text as well. After that, the clinical trial may be referred to as just “the trial”.

Voluntary participation

Participating in this trial is voluntary. If you decide to participate in the trial, please confirm your consent by signing the Consent Form. You can leave the trial and withdraw your consent at any time without giving any reason. This will not affect your right to receive any treatment that you may need.

- The fact that participating in medical research is voluntary is so important that it must be mentioned at the very beginning of the Information Sheet. Voluntary participation is generally regarded as an essential criterion for the societal acceptability of medical research. It must be clearly stated after the request to participate that participation is voluntary; that the subject may leave the trial and withdraw their consent if they choose; and that the participant’s right to treatment will not be impacted. These rights are enshrined in Article 29(2)a(ii) of the Clinical Trials Regulation and are derived from international declarations (e.g. the Declaration of Helsinki, specifically Articles 25 & 26), guidelines (ICH E6 [R3] 2.8.10l, effective from 23rd July 2025) and conventions (Oviedo Convention, Article 5).

You do not have to participate in this trial in order to receive treatment. Your physician will inform you about other treatment options for your illness (*this only applies to “patient trials”*).

- In Information Sheets intended for children, it is a good idea to make it as clear as possible that they are not obliged to participate.

Please take your time to read this Information Sheet. If you have any questions, contact the research physician or any other member of the research staff (contact information is given at the end of the document).

Sponsor, trial sites and principal investigators

This trial is carried out by (principal investigator, trial site, sponsor, implementing organisation). The data controller of the trial is X (*controller responsibility may be shared by more than one party*). They are responsible for ensuring that personal data are processed lawfully in the trial, and they will answer any questions about data protection and about disclosure of information as specified in data protection legislation.

- If Information Sheets are not prepared specifically for each trial site (in which case only the name of the trial site and the principal investigator there need to be stated here), then all trial sites in Finland and their principal investigators may be listed. However, this is not recommended if there is a large number of trial sites.

Background and purpose of the trial

The purpose of this clinical trial is to discover whether a particular (new) pharmaceutical substance / investigational preparation / investigational medicinal product / medication is effective and safe in the treatment/prevention/etc. of (*illness, type 2 diabetes, epilepsy, hypertension, etc.*). The trial is also intended to investigate (*other objectives of the trial*).

- The term to be used should be selected on a case-by-case basis, depending for instance on how well-known the medication in question is or whether medications are just mentioned generally.

The medicinal product (name) being investigated is a preparation that is expected to be effective in (*e.g. increasing insulin secretion in the pancreas to lower blood sugar levels*); or: the medicinal product is already being used to treat X, but its efficacy and tolerance have not previously been studied in the treatment of Y patients. Research on the medicinal product X is considered necessary because (*brief justification*).

(*If the trial is a placebo-controlled trial, this must be explained and justified at this point.*)

To date, this investigational medicinal product has been given to X persons.

The people being asked to join this trial are people who are X years old (*and who have coronary disease but no other conditions that may cause heart failure, etc.*), etc. Because the effects of the investigational medicinal product are not fully known, you may not join this trial if you are pregnant or breastfeeding or planning to become pregnant (*or equivalent wording*).

The trial will involve about X research participants in X countries. In Finland, there will be X participants in this trial.

- The template text is based on the description of conventional clinical trials conducted on patients. The instructions in this part should be modified as applicable, depending on the type of trial, its topic and its target group. If the trial is a combined trial on medicinal products and a medical device, this must be indicated at this point in the text.

- For example, the purpose and methods of a study involving healthy voluntary research participants may be radically different from those of a therapeutic trial.
- Clinical Trials Regulation, Article 2: "5) 'Investigational medicinal product' means a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial."
- The Information Sheet must spell out the primary objectives and the principal secondary objectives of the trial.
- The justifications and significance of the trial must be written up using neutral language.
- If the trial is placebo-controlled, this must be explained at this point in an understandable way.
- The target group of the trial must be described, but not all inclusion and exclusion criteria should be listed.

Research methods and trial procedures

- The trial setup and the methods used (including placebo control) must be described concisely and in general terms, in language understandable to a layperson.

If you decide to participate in the trial, participation will take about x days/weeks/years.

The trial includes x visits to the clinic. The research staff may also contact you by phone. In addition, your health will be monitored for a period of X days/months/years after the clinic appointments have ended (*also describe how the follow-ups are implemented*). During the trial, you can also contact the research staff yourself, for instance if changes occur in your health or if you need instructions on how to use the other medications used/needed during the trial (*describe where to find the contact details of the research staff*).

The trial will be performed as follows: (*describe the methods and arrangements used, the screening stage, the investigative treatment stage, the follow-up stage, control treatments, placebo use, randomisation, double blinding, the possibility and probability of being randomly assigned to the placebo group, and a statement that not even the researcher knows which medication the research participant will receive. If necessary, add information on the additional measures required for the trial compared to Standard of Care treatment.*)

- It must be possible for the potential participant to understand on the basis of the Information Sheet how many additional procedures will result from participating in the trial, compared to Standard of Care treatment. A concise general description of these procedures must be given.

During the trial, X blood tests will be taken, X medical examinations will be performed, etc. Additionally, the trial includes X procedures (*angiography, EKG, etc.*) to investigate... (*explain to the research participant the additional procedures required for the trial compared to Standard of Care treatment, extra appointments, journals and questionnaires to be filled in, prohibited medications, etc. State here if the research participant is not allowed to have any other treatments during the trial.*)

The trial includes genetic analysis, the purpose of which is (*explain the genetic test and how the samples will be used: pharmacogenetics, pharmacogenomics, etc.*). The purpose of genetic research is to

investigate whether genes have an effect on the effectiveness and safety of the medication (*or similar wording*). (*The genetic test may be presented in the Information Sheet proper. If so, it must be clearly stated that the genetic test is limited to the trial at hand and that the results will not be used for any other purpose.*)

If you choose to participate in the trial, you are requested to observe the following things during the trial that will affect your everyday life: (*special diets, contraception, exercise, etc.*).

If you decide to participate in the trial, you are expected to use reliable contraception throughout the trial (*or equivalent text. Further details may be given in the attachment to the Information Sheet.*) The investigator will inform you about permitted contraception methods (*provided that they are needed*). If you nevertheless become pregnant during the trial, data will be collected during your pregnancy as part of the safety monitoring of the trial. (*Also state here if data will be collected on the unborn child.*)

- If data will be collected on the research participant's partner during the participant's pregnancy, a separate Information Sheet and Consent Form must be issued for this.

- Reliable contraception methods must be listed in the Information Sheet specifically for each trial (particularly those involving teratogenic investigational medicinal products).

Potential benefits of the trial for the participant

At this point, it is not possible to assess reliably whether participating in this trial would be of benefit to you. However, useful information may be gained about the medication and illness studied. *(Describe for the potential participant whether they will be informed of the findings of the trial, of any "incidental" findings or of any other health information significant for the research participant. If research participants will not be informed of the findings, appropriate justification for this must be given. This may also be explained under "Ending of the trial".)*

Potential adverse reactions and inconvenience caused by the trial

The most severe and most common expected adverse reactions to this investigational medicinal product are (*explain the risks, known adverse reactions and significant discomforts of the medicinal product being investigated; **severe adverse reactions and their probability must be specifically explained.** Other adverse reactions may be explained in a separate appendix if necessary*).

- This section must include information on any adverse reactions associated with the investigational medicinal product (including any comparators) and also on adverse reactions and discomfort which will affect research participants' everyday lives and which thus may influence a decision to participate in the trial (e.g. restrictions on alcohol, particular foodstuffs or nutritional supplements). If research participants will not be receiving treatment according to the Current Care Guidelines or will have to discontinue previous treatments, this must be stated here. Information should also be given on whether there is a washout period and on any "emergency medication" specified. The potential participant must also be informed whether research participants will be required to fill in questionnaires on a daily and/or time-consuming basis. However, detailed instructions should be entered in the appendix to avoid the Information Sheet itself becoming too long. *The most severe and most common adverse reactions must be entered in the Information Sheet itself.*

The most severe and most common adverse reactions to and discomforts caused by the trial procedures are...

- E.g. a spinal tap. Descriptions of radiation exposure and radiation risk must be included in the Information Sheet itself. If the trial **will not cause** any additional radiation exposure compared to conventional treatment, this must also be stated in the Information Sheet.

Participating in the trial may also produce unexpected adverse reactions. These may be caused by the investigational medicinal product, by a procedure performed during the trial or by individual characteristics of the research participant (*you may add information on how potential adverse reactions may be mitigated*).

If new information about the investigational medicinal product is gained during the trial that is relevant for safety or for the continuing of the trial, the research physician will be in touch with you immediately to discuss whether the trial is to continue.

(*This information must also be provided concerning the comparators used in the trial.*)

Confidentiality and data protection

Personal data will be processed in this trial. Only personal data that are essential for the purpose of the trial will be entered in the trial register. Research on human subjects always involves collecting data on the research subjects in order to form an opinion about the properties and effects of a medicinal product. The identities of the research subjects are known only to the research staff, and they are all bound by confidentiality. All data and samples collected in this trial are pseudonymised. This means that they are encoded so that individuals cannot be identified. Unique identifiers such as name, personal identity number, etc., are replaced with codes. No data or samples can be associated with specific individuals in the trial's research findings, reports or publications. The unique identifiers are kept separate from the encoded data. The names, personal identity numbers and contact details of research subjects are not given to the sponsor of the trial (*except in the case of investigator-initiated studies*). (*Also explain here that information collected in the trial that is relevant for medical care will be entered in the patient information system.*)

- For special categories of personal data, the word 'race' (in Finnish, *rotu*) should not be used in the participant information sheet and informed consent form or in other materials directed at the research participant. The word 'rotu' is not appropriate for the Finnish operating environment. Instead, the term *ethnic background* may be used, as it is considered to encompass the terms (*race* and *ethnic origin*) mentioned in Article 9(1) of the *EU General Data Protection Regulation 2016/679* (GDPR).

As per section 33 of the Act on Clinical Trials on Medicinal Products, the legal grounds for the personal data processing are regarding measures essential for a clinical trial, public interest in general and public interest in the area of public health (GDPR Articles 6(1)e and 9(2)i), and regarding safety reporting and other notifications to the authorities, compliance with a legal obligation to which the data controller is subject and public interest in the area of public health (Articles 6(1)c and 9(2)i) (*AND/OR other grounds for processing pursuant to the GDPR as specified by the data controller*).

- The selected grounds for processing personal data must be described, and references to the GDPR must also be provided by article, paragraph and point. If the sponsor of the trial cites

"legitimate interest" as grounds for processing personal data (Article 6(1)f), then it must be stated in the text that a balance test has been performed (and the test must be briefly described).

In the research findings and in all other documents, research participants are referred to only by codes. The register will be kept for at least 25 years (*after the end of the trial; for as long as required in the marketing authorisation for the medicinal product or by other regulation, etc.*). Data on health and other data necessary for the trial may also be obtained from other healthcare operating units and personal registers containing health data (*specify which registers and what data*). Representatives of the Finnish Medicines Agency (FIMEA), of supervisory authorities in other EU and EEA Member States and of the sponsor of the trial are allowed to access personal data only for the purpose of ensuring that the trial has been conducted in accordance with the research plan and good clinical practice. (*In global studies, supervisory authorities from outside the EU and EEA may also have the right to review and process personal data related to the clinical trial under the responsibility and supervision of the principal investigator.*) Trial data may also be disclosed to the pharmaceutical supervisory authority for the purpose of applying for a marketing authorisation.

- If personal data (patient data) collected in the trial will be confirmed using direct remote access to confidential health records, this must be stated in the Information Sheet.

Data will be transferred in encrypted form to countries outside the EU/EEA *(list the known countries)*, where data protection is not necessarily at the same level as in the EU. In this case, the sponsor of the trial will ensure that the personal data are transferred appropriately *(on the basis of a decision by the Commission pursuant to GDPR Article 45, legally binding corporate rules pursuant to GDPR Article 47, standard protection clauses pursuant to GDPR Article 46(2) or derogations and protective measures pursuant to GDPR Article 49)*.

Personal data may also be disclosed to (*another researcher, another sponsor as the result of a corporate transaction, etc.*) in the interests of the original purpose of the trial. Even in this case, all parties involved are bound by the confidentiality requirements described above. (*It may also be underlined here that data will not be disclosed to any other parties.*)

If a participant decides to leave the trial, or if the investigator decides to discontinue the trial, the data collected up to that point will be used as part of the research material. This is vital for ensuring the reliability of the trial findings and for ensuring the safety of the research participants.

Research participants have the right to inspect the collected personal data and to request corrections to be made if necessary. Participants must also be told, on request, where the data have been collected from and where the data and/or samples have been delivered to (*you may add a note to the effect that inspecting personal data is in many cases not possible until the trial has ended*).

- This section explains the rights of the data subject the exercising of which has real consequences. The potential of data subjects to exercise their rights in respect of the processing of their personal data varies depending on the grounds for processing. For more information on the various rights of data subjects depending on the grounds for processing, please visit the website of the Office of the Data Protection Ombudsman: https://tietosuoja.fi/en/what-rights-do-data-subjects-have-in-different-situations.

Contact details of the data controller's data protection officer: _____
(Please make sure that it is possible to conduct this business in English.)

- The language of communication must be the same as in the consent procedure.

Any research participant who considers that their personal data have been processed in violation of the GDPR or of the Data Protection Act (1050/2018) may file a complaint with the supervisory authority (in Finland, this is the Data Protection Ombudsman, Lintulahdenkuja 4 (PO Box 800), FI-00531 Helsinki, tel. 0295666700, email: tietosuoja(at)om.fi).

Cost of the trial and financial statements

The investigational medicinal product and any procedures performed in the trial are free of charge to the participant. Any travel expenses that may incur because of examinations will be compensated at actual cost on the basis of receipts submitted.

- If the control is Standard of Care treatment, it must be stated here that it is also provided free of charge (outpatient clinic fees are covered, etc.).

- If a research participant is to be compensated for loss of income and/or for inconvenience, this must be explained at this point (compensation for inconvenience also needs to be justified).

(You may also explain whether the expenses of any accompanying person or guardian will be compensated.)

The trial is being financed by XXX. XXX pays the research centre a fee for carrying out the trial. The investigator and other staff are paid (*or not paid*) a separate compensation for carrying out the trial (*or similar explanation*). *(Explain the researchers' links to the sponsor or executor of the trial and any other relevant financial interests (e.g. invention, patent application, setting up a company of their own).)*

Insurance cover for research participant

If you suffer personal injury because of the investigational medicinal product or because of a procedure performed in the trial, you can claim compensation.

If you suffer an injury, you may apply to Pharmaceutical Injuries Insurance for compensation. Pharmaceutical Injuries Insurance pays out compensation for unexpected adverse reactions caused by investigational medicinal products, as further specified in the terms and conditions of the insurance. *(If the medicine is not covered by Pharmaceutical Injuries Insurance and other insurance cover has been taken out for research participants, this paragraph must be amended accordingly.)*

For personal injuries other than those caused by the investigational medicinal product, you may claim compensation under the trial site's patient insurance. Patient insurance pays out compensation for personal injury caused in the context of healthcare and medical care, under the conditions specified in the Patient Insurance Act. The Patient Insurance Centre is responsible for handling compensation claims for patient injuries.

If you need more information about patient insurance, ask the patient ombudsperson at the trial site, for instance.

- The text in this section is written with the Finnish operating environment in mind and should be retained as is. Contact details for the patient ombudsperson or instructions how to make contact may be added to the final paragraph.

Ending or discontinuing the trial

The investigator will talk to you about your treatment after the trial ends (*only in treatment-related trials*). After the trial ends, you will be informed which medicine or investigational medicinal product you were given during the trial. Information on the trial and a summary of the findings will be published in the EU database https://euclinicaltrials.eu/.

- If research participants are not to be given the aforementioned information after the trial, there must be a good reason for this, and it must be explained in the Information Sheet.

- If databases other than the EU database are also used, the EU database must be mentioned first.

In some cases, the investigator or the sponsor of the trial may have to discontinue your participation before the trial ends. If this happens, the necessary measures will be discussed with you.

Further information

For further information about the trial, you can consult the investigator or anyone else on the research staff. You can talk to them about any adverse effects or symptoms presenting during the trial, about the processing of your personal data, etc.

Contact details:
(enter the contact details of the investigator/research staff here)

CONSENT TO A CLINICAL TRIAL ON MEDICINAL PRODUCT(S)

I have been asked to participate in the clinical trial on medicinal product(s) *(unambiguous identification of the trial i.e. name, code and EU trial number)*.

I have read the Information Sheet of the trial and have received enough information on the trial and on the collecting, processing and disclosure of personal data in the trial. The content of the trial has also been explained to me in person, and I have had satisfactory answers to all the questions I have asked about the trial. The explanations were given by _____ *(name of person)*. I have had enough time to consider whether to participate in the trial.

I understand that participating in this trial is voluntary.

I have the right to withdraw from the trial at any point during the trial and without giving any reason. There will be no negative consequences for me withdrawing from the trial. It will not affect my status as a healthcare client. I am aware that the data on me collected before my withdrawal will be used as part of the research material and in the evaluation of the safety of the medicine in question.

By my signature, I confirm that I will participate in the trial described in this document and voluntarily consent to being a research participant. I am aware that my personal data may be processed for the purpose of an inspection conducted by a foreign authority and in the context of quality assurance by a representative of the trial sponsor.

_____ _____

Signature Date

_____

Name in block letters

Consent received

_____ _____

Signature of the person receiving the consent Date

_____

Name in block letters

The original signed document is to remain in the archive of the investigator, while a copy is to be given to the research participant or their representative.

Version history

Date	Description/Modification
6.5.2025	A comprehensive review of the content of the guideline, including clarifications of the text sections on benefits and potential adverse reactions and inconvenience as well as a mention of decentralized trials. Justifications and clarifications were also added as a new element to the template text.
25.6.2026	Mainly a technical update, including changes related to document accessibility. In addition, clarifications have been added to the guideline regarding the use of the word ‘race’ and consent procedures in accordance with GCP guidelines.