**ICF TEMPLATE FOR INTERVENTIONAL CLINICAL TRIALS WITH TRIAL MEDICINE IN HEALTHY ADULT PARTICIPANTS**

# GUIDANCE

## Purpose of the template and how to use it

The purpose of this template is to produce an informed consent form (ICF) for healthy adult participants taking part in an interventional clinical trial with a trial medicine (Ref.[[1]](#endnote-1)), henceforth referred to as “trial”. (The Dutch and French templates use the terms “klinische studie/studie” and “étude clinique/étude” [clinical trial/trial] instead of the legal terms “klinische proef/proef” and “essai clinique/essai” [clinical trial/trial], which are less known to lay persons.)

This template is available in three languages: English, French and Dutch. The sponsor must submit the ICF to the Ethics Committee in the official national languages of the region where participants will be recruited.

The following colour codes are used:

* purple: the text is mandatory and can only be amended for justified reasons. The sponsor must add a statement to the submission file describing which version of the ICF template was used, and (if applicable) what changes have been made to any of the passages in purple and why. A template for this statement is available on the website of the CT College ([documents/sponsor-statement-template](https://consultativebodies.health.belgium.be/en/documents/sponsor-statement-template)). To simplify the evaluation by the Ethics Committee it is requested to highlight any amended text in yellow or use track changes.
* black: the text is a proposal and can be adapted as required for the particular trial.
* blue: the text must be replaced with trial-specific details.
* red: the text contains guidelines for the sponsor on how the section should be completed. This text must be deleted as well as this part of the document with guidelines.

The footer of the document can be adapted as preferred by the sponsor.

The template contains “fields” and “cross references” which can be updated in MS-WORD via F9 or via right-mouse click and selecting “Update Field”. (In order to update all the references in a document, select the entire document (press Ctrl A in MS-WORD) and then press F9.)

## Editorial advice

The ICF must be written in a **language that is** **clear and understandable** for the participant. The document must be readable for and understood by people who are not healthcare professionals and who have not been given a verbal explanation. It must be comprehensible for people with a mental capacity of a 12-year-old.

Kindly take into account the following advice:

* 1. Use correct sentence structure (beware of literal translations from English to French/Dutch, incorrect use of terms etc.).
	2. Use short sentences (ideally less than 12 words) and short paragraphs (ideally less than 7 lines). If possible, use *bullet points*.
	3. Avoid technical jargon.
	4. Use the same terminology for the same concept throughout the entire document. This template, for example, uses the following terms:
		+ “Clinical trial” or “trial” (instead of research, trial…)
		+ “Trial staff” (instead of research team, trial team, personnel,…)
		+ “Investigator” for the healthcare professional in charge of the trial
		+ The purple text in the template uses the more popular term “encoding” instead of “pseudonymising”. In order to avoid confusion, use these terms in the trial-specific text as well.
		+ The template uses the term “emergency card”. The sponsor can replace this term with a different concept, as the name depends on the sponsor.
		+ The French template uses the expression “devenir enceinte” [get pregnant] instead of “tomber enceinte” [fall pregnant]. Use these terms in the French trial-specific text as well.
	5. Avoid excessive use of abbreviations and, if needed, explain any abbreviations used. Always write out the first usage of the abbreviation in full and put the abbreviation in brackets after that first instance.
	6. Use a clear and sufficiently large font:
		+ When printing on A4 in one or two columns, preferably use font ≥ Arial 12;
		+ When printing as a leaflet, the margins should be reduced and the font increased to ≥ Arial 16.
	7. Use an attractive design with sufficient (sub-)headings and white space.
	8. If possible, involve a healthy volunteer in the development of the ICF (with regards to understandability and relevance of the information).
	9. Please state the same ICF version number and issue date on all pages of the document.
	10. Please number all the pages of the document in the format “page X/Y”, where Y represents the total number of pages.

For ICF’s in Dutch, please refer to the information “Schrijfadviezen voor de geneesmiddelenbijsluiter” [Recommendation for writing package leaflets] (Utrecht University) and “Patiëntvriendelijke termen” [Patient-friendly terms] of the Medicines Evaluation Board (CBG-MEB), via the following link: <https://www.cbg-meb.nl/onderwerpen/hv-patientenbijsluiter>.

For English ICFs, please refer to the recommendations for writing “Summaries of Clinical Trial Results for Laypersons”, available via the following link: <https://health.ec.europa.eu/system/files/2020-02/2017_01_26_summaries_of_ct_results_for_laypersons_0.pdf>

Many of these recommendations also apply to ICF’s in languages other than English.

For ICFs in French, please refer to FALC, “Facile à Lire et à Comprendre” [Easy to read and understand]: <https://www.falc.be/>

## Front page

The front page of the template contains the minimum information required on the front page of an ICF. The sponsor is allowed to add additional information. However, inclusion of the contact details of the Data Protection Officer (DPO) of the sponsor is not permitted (The sponsor does not know the participants and can therefore not advise them concerning their rights.).

All details are specific to the trial centre, apart from details of the CT College, the sponsor's insurance company and the Belgian Data Protection Authority (DPA). Contact details specific to the trial centre are to be added after the ICF has been approved by the Ethics Committee. If the trial is a single-centre trial, details can be entered prior to the submission, but please note that the details would need to be deleted if any sites are added later on by amendment.

The phone number given for "Trial staff, emergency contact", should be a trial centre/hospital number (e.g. general number) which allows participants to contact the on-call physician for urgent questions about their health 24/7. If needed, the on-call physician will contact the trial staff. The telephone number given here should not be the one of the Emergency Department at the hospital.

In certain situations, there may not be a Data Protection Officer (DPO) or ombudsperson for patient rights available at the trial centre, e.g. for studies that are conducted within private practices. In these cases only, the following provisions apply.

- If no official ‘data protection officer of the trial centre’ has been appointed, the text in the table of contact persons can be replaced by the ‘Contact person for data protection’.

This may be a person who is responsible for the protection of the personal data within the trial centre; for example, this could be the principal investigator.

- The “ombudsperson for patient rights” can be replaced with the CT-College:

|  |  |
| --- | --- |
| The “ombudsperson for patient rights” can then be replaced with the “CT-College”. | Email:ct.college@health.fgov.be |

*ICF template version 1.0 was created on behalf of Healixia (the Belgian community of all professionals active along the life cycle of medicines, medical devices, in vitro diagnostics & other health related products) by a working group consisting of representatives of the various phase 1 units in Belgium.*

*BAREC (Belgian Association of Research Ethics Committees) and pharma.be (the Belgian association of the innovative (bio)pharmaceutical industry) were consulted*

ICF template version 1.0 was approved by the BAREC Board on XX/XX/2024 and by the College Board on 24/01/2025 to meet the requirements for clinical trials.

# TEMPLATE

|  |  |
| --- | --- |
| INFORMED CONSENT FORM FOR CLINICAL STUDIES WITH A TRIAL MEDICINE IN HEALTHY ADULT PARTICIPANTS | [optional]TrialTrial site/hospital logo |

Screening number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# [FRONT PAGES]

*The official lay title of the trial as given in the CTIS database*

Official title of the trial: *Official title*

EU CT number: *Official EU CT number*

Trial number: *sponsor trial number [optional:] trial centre trial number*

Sponsor of the trial: *Name and address of the company, hospital, university or other organisation*

[If applicable (Ref.[[2]](#endnote-2)):]European representative: *Name and address of the European representative*

[If applicable] Company working on behalf of the sponsor*: Name and address of the CRO*

Name of trial centre: *official name of the trial centre [as given on the website of the Federal Public Service (FPS) Health, Food Chain Safety and Environment (*[*NL*](https://www.health.belgium.be/nl/gezondheid/organisatie-van-de-gezondheidszorg/delen-van-gezondheidsgegevens/gezondheidszorginstellingen)*)]*

Main address of the trial centre: *address of the trial centre*

[Optional] Trial centre number: *enter trial centre accreditation number*

Principal Investigator: *Name of the principal investigator*

 [State the version number in the footer of the ICF so that it appears on every page of the document.]

## **Version history**

[When a new version of the ICF is created, complete the revision history table below to inform participants of the essential changes. This revision table is useful for both the ethics committee(s) and participants.]

|  |  |  |
| --- | --- | --- |
| **Version number** | **Version date**  | **Description of changes** |
| 1.0 | dd-mmm-yyyy | Initial version |
| 2.0 | dd-mmm-yyyy | E.g. I.4.1. Addition of a few side effects |
| 3.0 | dd-mmm-yyyy | E.g. I.8. Change because of a new law |

## Whom can I contact if I have any questions?

[The sponsor can choose to include the table below here or at the end of the ICF.]

|  |  |  |  |
| --- | --- | --- | --- |
| **For** | **Name** | **Job title** | **Contact details** |
| Information and concerns about your participation in the trial or your (general) health | First name, surname | Principal investigator of the trial centre | Telephone number/ E-mail |
| Information, problems, concerns |  | Trial staff | Telephone number |
| Urgent questions about the trial |  | The emergency contact person of the trial staff [not the emergency department at the hospital] | Telephone number |
| Concerns/questions about your rights as a participant in a clinical trial |  | Ombudsperson for patient rights of the trial centre [and if not possible, contact the CT College] | Telephone number of the trial centre [if not possible: ct-college@health.fgov.be] |
| Dispute or complaint about a damage claim (demand for compensation) | Name and address of the insurance company of the sponsor  | Insurance company of the sponsor | Policy number:numberAddress: address of the insurance companyTelephone number: E-mail: e-mail address: [Add at least 1 contact method alongside the address] |
| Questions about the confidentiality of your data |  | Data Protection Officer of the **trial centre** [or if not possible: Contact person for data protection . | Telephone numberEmail: email |
| Complaints about the confidentiality of your data |  | Belgian Data Protection Authority (DPA) | Telephone number: +32 (0)2 274 48 00Email: contact@apd-gba.be  |

* *To manage complaints that cannot be resolved by the investigator, contact the ombudsperson of the trial centre at the address above.*
* *According to the* *General Data Protection Regulation (GDPR), you have the right to access your data. If you have any questions about this, you can contact the Data Protection Officer of the trial centre at the address above.*
* *You also have the right to lodge a complaint on the way your data were processed with the Belgian Data Protection Authority (PDA). This is the Belgian supervisory authority: it is responsible for compliance with data protection legislation.*

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# THE TRIAL AT A GLANCE

[In this chapter, please include a brief summary (maximum 2-3 pages) of the most important aspects of the trial. Use very simple words in this chapter, so that the text is understandable for everyone. The overview below is an example. Depending on the trial design, the table and pictograms can be adapted or a format more suitable for the trial can be used].

The overview below will already give you an idea of what this trial contains. We still want to ask you **to read all the pages**, even if it will take you quite some time. It is important that you read and understand everything, so you know what the trial contains. If you have any questions, feel free to ask the trial staff. We will be happy to answer them.

|  |
| --- |
| A picture containing room  Description generated with very high confidenceTrial medicine: <name>Developed for the treatment of <add indication in layman’s language>Give the following information: whether it has been approved by Belgian authorities and/or in other countries and whether the product is already available on the Belgian market (with or without prescription) and whether the medicine has previously been tested on humans. If not, state that this is the first trial that administrates this trial medicine in humans.The trial medicine is taken by mouth/injection/… as a tablet/solution/…. You will receive <X> administrations of the trial medicine over a period of <Y months/weeks/days>. |
| A picture containing room  Description generated with very high confidenceIt is extremely important that you know that all medicines may have side effects. Those side effects may be serious. This is why it is important that you **report** **every health problem to the trial staff**.The trial staff will also regularly ask you questions about your health. |
| A picture containing room  Description generated with very high confidenceThe trial staff will perform a series of tests on you during your participation in the trial. State any specific procedures here, referring to the section containing further details. |
| A picture containing room  Description generated with very high confidenceBlood samples will be taken. The total estimated volume of blood that will be taken for this trial is <X> ml over a period of <x> weeks/months. [Add info on all other types of samples (urine, faeces, …), including additional samples].  |
| A picture containing room  Description generated with very high confidenceFollow the instructions that the trial staff gives you. |
| A picture containing room  Description generated with very high confidenceYou will need to come to the trial centre <X> times. There are <Y> overnight stays. The total duration of the trial is <Z> days/weeks/months/years. |
| A picture containing room  Description generated with very high confidenceA picture containing room  Description generated with very high confidenceYou will be asked to complete an electronic and/or paper diary to monitor your health/intake of the trial medicine. |

# CHAPTER I – DESCRIPTION OF THE TRIAL AND YOUR RIGHTS DURING PARTICIPATION

## Introduction

You are invited to participate in a clinical trial. New medicines need to be tested in clinical studies before they can be approved by government authorities. These authorities want to be sure that new treatments are safe and that they work.

The purpose of this trial is to investigate the [optional: experimental] medicine <name of the trial medicine>. [optional: An experimental medicine is a medicine that is still being investigated to evaluate its efficacy, safety and/or mode of action.]

As you are a healthy volunteer and you therefore do not have the condition the medicine is intended for, you will not experience any beneficial effects of the treatment yourself.

This informed consent form provides further details of the trial itself and describes exactly what your participation involves. The trial staff will go over this form with you and provide you with further information where needed. If there is anything you do not understand, please do not hesitate to ask.

Please read this document carefully and take all the time you need before deciding whether or not you want to participate in this trial.

**Your participation in this trial happens voluntarily and you should never feel pressured**. This means that you have the right not to participate in the trial. You may withdraw at any time without needing to give a reason for this, even if you have previously consented to participate. However, it is advisable for your safety to inform the investigator if you have decided to stop participating in the trial. Your decision will never affect your relationship with the investigator and the trial staff.

If you consent to participate, you will be asked to sign this consent form. If you participate in this trial, we advise you to let your general practitioner (GP) know.

## What is the purpose and design of the trial?

[These are the topics you could cover:

* Why is this trial being performed?
	+ What is the disease/indication?
	+ Why is a trial medicine needed? Are there alternatives available?
	+ How does the trial medicine work?
	+ Has the trial medicine been tested on humans?
	+ Whether the medicine has been approved by Belgian health authorities and/or in other countries and whether it is available on the market (in the trade) (prescription or non-prescription)
* What is the purpose of the trial?
	+ Primary purpose of the trial:
		- Safety
		- To measure what happens when the medicine travels through the body
		- Dosage range
		- ….
	+ Number of people in the trial + where the trial medicine is being/has been tested (multiple sites/countries etc.)
	+ Brief description of the trial design using words that the participant can understand. Explain what randomised/blind/cross-over trial/placebo/screening is, where the trial medicine(s) is/are being compared to a placebo and/or a reference medicine. If applicable, add information about the probability of being assigned randomly to the treatment (= the probability the participant receives a certain treatment e.g. 1 in 6 participants receives the placebo).
	+ Dose and form of administration
* Inclusion/exclusion criteria or proposal to add the sentence: The investigator and/or trial staff will discuss the conditions for participation with you.

During your first trial visit, all the inclusion/exclusion criteria will be reviewed and discussed. You will be asked to give truthful answers to all questions the investigator and/or the trial staff ask you. By agreeing to participate in this trial, you understand that not or incorrectly informing the investigator and/or trial staff could be harmful for you.

* If anny difficult words are used, they should be explained in layman’s language. The following website may help: <https://www.ema.europa.eu/en/about-us/glossaries>]

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## What will happen during the trial?

[Description of what will happen during the trial:

* The timing + number of the various visits, the duration of the stays and the estimated total duration of the trial
* The various tests, procedures and interviews that will be performed
* Method of administration of the trial medicine (route, after fasting or after a meal, formulation, ...)
* Meals that may or may not need to be eaten completely
* What sampling (blood/urine/saliva...) will happen and why (safety, PK, genetic research, drug screening, pregnancy...) and whether a catheter will be used
* Possible unplanned visits or early-termination visits.
* State the estimated blood volume that will be collected during the trial and compare this to a blood donation. If greater than a blood donation, describe the potential risk for the participant in section ‎5.3 on risks. Also state whether additional blood may be taken for safety tests and/or in the event of technical problems.
* Also state whether the protocol permits moving or omitting actions/samples and/or if the dose may be adjusted.

Add a schedule containing an overview of the visits/stays and the actions. If using the protocol schedule, ensure that any words in that schedule are changed to layman’s language and if needed add further information.]

Note: it is not acceptable to add any statements in this text (or elsewhere) that could intimidate or influence the participant in their decision whether or not to participate or continue to participate, e.g. “The sponsor could trace you if you decide to stop your participation...” or “we will use any means necessary to trace you...” etc.]

## Will I benefit from the trial?

As a healthy participant, your own health will not benefit from your participation in this trial.

The results of the trial will lead to new understanding of the effect of the trial medicine and may be of great importance for the development of medicines and treatments that may benefit future patients.

## What are the possible risks and discomforts of participation in the trial?

Participation in a trial always involves some risk. Any medicine can have side effects. Some of those are known, others are not. You may also experience discomforts from the trial procedures themselves. The trial staff is trained to take the appropriate measures and to limit risks and any possible discomforts.

* 1. What are the possible side effects and risks of [name of the trial medicine(s)] [if applicable:] and [name of reference medicine(s)]?

Below are the discomforts and risks that have been established after administration of the trial medicine. These were established in [Select:] previous studies [AND/OR:] animal studies [OR]: medicines with the same mechanism of action. It is possible that you may also experience those. If you have any side effects, be sure to let the trial staff know.

[If there are any references to animal data, state that those are not always applicable to humans. Also state whether or not there is information available on side effects in humans. If there is no information available yet, please clarify by comparing the animal dose to the human dose (e.g. the maximum dose in this trial is x times lower than the maximum dose tested on animals) and provide details of the tolerability in animals and the estimated safety in humans.]

[Per trial medicine/reference medicine: add a list of side effects and describe them briefly. Give the side effects in order of frequency. Describe any irreversible side effects separately in bold.]

[The frequency of side effects must be quantified in an understandable manner for participants. The frequency may not be available for **early phase studies**.]

|  |  |
| --- | --- |
| Very common | In more than 1 in 10 people |
| Common | In 1 in 10 to 100 people |
| Less common | In 1 in 100 to 1000 people |
| Rare | In 1 in 1000 to 10,000 people |
| Very rare | In 1 to 10,000 to 100,000 people |

[If there are certain risks participants should be aware of (including the associated symptoms) to enable appropriate treatment to be given rapidly, these can be described in an additional paragraph, e.g. symptoms of a severe allergic reaction to the trial medicine.]

[Describe here how possible side effects will be monitored (e.g. observation during the period after the trial medicine has been administered using clinical evaluation (physical examination and medical history), laboratory parameters, vital signs (blood pressure and heart rate), measurement of body temperature and/or heart function, signs of anaphylaxis).]

As this trial medicine is still being investigated, there may be other, currently unknown, risks and discomforts that may occur. **This is why it is very important that you immediately report any new or worsening health problem to the investigator. This also applies if you think that that this has nothing to do with the trial (or to [name of trial medicine/reference medicine]) and even if it has already been described in this document. If you, for whatever reason**, **consult another doctor during the trial, you must let him/her know that you are participating in a trial and show your “emergency card”. This may be important for a correct diagnosis and treatment if needed.**

* 1. Am I permitted to use other medicines during the trial?

Some foods and/or beverages, as well as some medicines (including vitamins and herbal remedies), may disturb the way your body processes the trial medicine. This could make the amount of trial medicine in your body higher or lower than what is expected as normal. If you use medicines or supplements, the use of the trial medicine may also disturb the way in which your medicines and/or supplements work. It is very important that you inform the investigator about all medicines and/or supplements you use during the trial. If you need to use other medicines, discuss this with the investigator before you start using them.

[Describe the restrictions on concomitant medicines and/or whether there are exceptions (e.g. paracetamol or ibuprofen) here.]

* 1. What are the possible risks or discomforts of the trial procedures during the trial?

[Add risks, discomforts, precautions (e.g. no driving) associated with the specific tests that will be performed as part of the trial. This also applies to the tests participants are likely already familiar with (e.g. X-rays, MRI, biopsy, COVID-19 swab, blood sampling, ECG, fasting, ...). State the additional radiation dose of the tests compared to the natural background radiation and the risks associated with this additional radiation dose. Please use the FANC-approved text available on <https://www.belnuc.be/tools/> and the link there named “Consensus text on radiation burden for inclusion in ICF concerning diagnostic clinical trials using radiopharmaceuticals in healthy volunteers and patients” as a reference.]

|  |  |
| --- | --- |
| **Procedure** | **Discomfort and/or risk** |
| Blood sampling | Blood sampling may cause pain, bleeding, bruising or localised inflammation at the blood sampling site. Some participants may also feel dizzy or even faint during the procedure. The staff who take the blood will do all they can to limit/avoid these discomforts.[If the estimated blood volume is no more than 500 ml]: The total amount of blood that will be collected is not associated with a risk to your health, as long as you did not donate more than XXX ml of blood or lose considerable amounts of blood in the XX days before the first scheduled administration of the trial medicine.[If the blood volume is higher than a blood donation (500 ml), state the possible risks for the participant] |
| … | … |

[For studies with biopsies: specify the number of biopsies, site in the body and the risks per site in the body,…]

* 1. Will my participation in the trial influence my daily activities?

If you choose to participate in the trial, there are also restrictions you need to adhere to during your participation in the trial, specifically:

* You cannot participate in another clinical trial (other clinical studies means research with trial medications, medical devices, medical equipment or surgical techniques).
* [If applicable: describe the additional burden for the participant: the impact on or restrictions in daily life (e.g. not allowed to travel, play sport, consume alcohol or tobacco, use certain foods or drinks, ...).]

## What do I need to know about contraception, pregnancy and breast-feeding? [Adapt this section to the trial requirements]

* Women participating in the trial should understand that exposure of the foetus to the trial medicine may involve a risk for the unborn child.

The risk perception for men participating in the trial may be less obvious. It is therefore necessary to explain that the medicine may have a potentially harmful effect on sperm quality and could therefore involve a risk for the development of the foetus in the event of pregnancy.

* The information about these risks should clarify for both female and male participants that pregnancy in a participant or the partner of a male participant should be avoided.
* If there is no risk and male participants do not need to take contraceptive measures, then this should be stated here.

If contraceptive measures are precautionary without knowledge of any harmful effects on sperm quality, participants must be informed about this.

* State any measures to be taken if the partner of a male participant gets pregnant (despite all precautions).
	+ If the partner of a male participant gets pregnant, the participant should be encouraged to inform the investigator of this, so that the best option can be chosen for her and the foetus/baby, an option which may involve being included in a monitoring programme.
	+ The pregnant partner must be informed about collection of personal health data (course of the pregnancy, birth and first months of life of the unborn child, if applicable).
	+ A separate ICF, which needs to be reviewed by the Ethics Committee, clarifies the reasons for monitoring the pregnancy and therefore the risks for the unborn child. It also states the rights of the female participant (if participating) in this monitoring programme (that participation is voluntary, that consent can be withdrawn, privacy protection, liability for damages).
	+ If the sponsor has reasons to suspect a harmful effect, this information must be stated explicitly.
	+ Depending on the extent of the risk, it is also important to insist that the participant informs his partner(s) of his participation in a clinical trial with a medicine that may be harmful for a foetus and about the contraceptive measures they must take together.
	+ If applicable, the male participant should also be informed that he must absolutely not donate any sperm.
* State any measures to be taken if the female participant gets pregnant (despite all precautions).
	+ Mention the follow-up measures described in the protocol.

[If applicable] This part is only for female participants of childbearing potential or for male participants who could make their female partners pregnant.

Female participant: Because the effects of [name of the trial medicine and/or reference medicine] on an unborn child or baby are not known, you cannot participate in this trial in case

* You are pregnant,
* You want to get pregnant in the near future or
* You are breast-feeding.

Donating egg cells is also not permitted during and after your participation in the trial, until [number of] days/months after the last administration of the trial medicine.

If you participate in the trial, you will need to use one of the [select: following [or] permitted] contraceptives: [If applicable: give a list of the permitted methods]. You will need to use one of these permitted contraceptives from at least [number of] days/months before the first administration of the trial medicine until [number of] days/months after the last administration of the trial medicine. The contraceptive used must be effective before the trial medicine is administered. Please discuss this topic with the investigator if this applies to you. Please inform the investigator if you decide to change contraceptives during the trial.

If you still get pregnant during the trial, then tell the trial staff immediately. The investigator will then discuss the options with you [optional: and with your partner]. For safety reasons, the investigator would like to monitor your pregnancy and its outcome. He/she may be obliged to share these data with the sponsor to meet regulatory requirements on monitoring and reporting safety information on the product. [If applicable: If your baby is also monitored after birth, you will be asked to sign a specific informed consent form.]

Male participant:

[Example in the event of risk] Taking [name of trial medicine] could have an effect on your sperm and could involve an unknown risk for an unborn child. You cannot participate if you and your partner are planning a pregnancy during the trial.

If you participate in this trial, you will need to use a contraceptive from at least [number of] days/months before the [first] administration of the trial medicine until [number of] days/months after the last administration of the trial medicine. Please discuss this topic with the investigator if this applies to you.

Donating sperm is also not permitted during and after your participation in the trial, until [number of] days/months after the last administration of the trial medicine.

If your partner is pregnant or breast-feeding, you should abstain from sex or use a condom during the trial and for [number of] days/months after you stop using the trial medicine.

You are committing yourself to inform your female partner about your participation in this trial and about the possible risk for an unborn child.

If your partner still gets pregnant during the trial, you will need to inform the investigator immediately. With your consent, the investigator will ask your partner to be able to monitor her pregnancy and its outcome and to sign a specific informed consent form (for the pregnant partner). [If applicable: If your baby is also monitored after birth, you will also need to sign the specific form.]

## What if anything goes wrong during the trial?

Even if there is no fault, the sponsor is liable for damage you have suffered, directly or indirectly related to your participation in the clinical trial. The sponsor has taken out appropriate insurance (called no-fault insurance) for this liability (Ref.[[3]](#endnote-3)). A copy of the insurance certificate is available from the investigator or the trial staff.

If you (or in the event of death, your rightful claimants) want to claim compensation for damage to your health as a direct or indirect result of participation in the clinical trial, you must immediately inform the trial staff of this.

If the investigator is of the opinion that there may be a link between new or worsening health problem(s) and the clinical trial, he/she will inform the sponsor of the clinical trial about this. The sponsor will then immediately start the declaration procedure with the insurance company. If the company considers this necessary, it will appoint an expert to establish whether there is a link between your reported health problem(s) and the clinical trial.

If you feel this is appropriate or if you or your rightful claimants disagree with the investigator or with the expert appointed by the insurance company, you can contact the insurance company or start proceedings against the insurance company. The contact details are given on the front page of this form [OR] at the end of the document.

## What if new information about the trial medicine or the trial becomes available during the trial?

Important new information could become available during the course of the trial, which could influence your decision to (continue to) participate, such as information about the trial medicine or the possible side effects. It is the duty of the investigator to discuss this new information with you and to give you the opportunity to reconsider your participation in the trial. In that case you will be asked to sign a new consent form.

## Can my participation in the trial end early?

As discussed in detail further along in this section, your participation in the trial may end early if

* You decide to withdraw your consent or to stop taking the trial medicine,
* The trial doctor decides to stop your participation in the trial, or
* Other authorities suspend or end the trial.

In each case, if your participation in the trial ends early, the investigator will discuss your possible further follow-up with you. The data collected before your participation ended will be used further as described in this form. This is to avoid incorrect interpretation of the trial results (as described in paragraph I.§ ‎11.4).

Depending on your situation, the investigator will discuss with you whether follow-up visits or procedures are needed. You only need to attend this/these follow-up visit(s) or have these procedures done if you are willing to do so.

If you experience a new side effect after the end of your participation in the trial, you can contact the investigator and ask for possible follow-up of this.

* 1. You decide to withdraw your consent

Your participation is completely voluntary. You can decide to withdraw your consent at any time without giving a reason. For your own safety, you should however inform the investigator about your decision. Even if this is not mandatory, it may be useful for the investigator and for the sponsor to know the reason for your decision (e.g. side effects, too much travel, ...).

If you withdraw your consent, this means that you decide to stop

* Using the trial medicine, and
* All the trial-related visits and examinations.

No further new data will be collected and passed on to the sponsor.

If your biological samples (e.g. blood samples, urine samples) have already been used or tested before you withdraw your consent, the sponsor still has the right to use the results of those tests.

Your biological samples collected (but not yet tested) before you withdraw your consent and the data obtained can still be used by the sponsor. You can ask to have these samples destroyed. In order to avoid incorrect interpretation of the trial results, this may be postponed until the end of the trial.

[If applicable:] If you have given any additional consent for the use of your samples for future research and you do not withdraw this additional consent, your samples may still be used for that research.

* 1. [optional] You decide to stop taking the trial medicine

If you want to stop taking the trial medicine, but consent to continue to participate in the trial visits/procedures, the investigator will discuss with you whether you can stay in the trial.

[In that case, please clearly document this consent and the form of consent (visits, telephone contact only, ...).]

* 1. The investigator decides to stop your participation in the trial

The investigator may decide to stop your participation in the trial if

* He/she considers it in your best interest (e.g. based on your test results, if you develop certain health problems, [If there are participants who could get pregnant: if the protocol defines that you should not get pregnant, but you still became pregnant,] …)
* You do not follow the instructions of the trial staff and/or the trial [optional: and/or the house rules of the trial centre],
* There is another reason, which will be explained to you, or
* The entire trial needs to be stopped for all participants (see next paragraph).

If that happens, the trial staff will explain why and ensure appropriate follow-up.

* 1. Other authorities may suspend or end the trial

The sponsor and the competent Belgian health authorities may suspend or end the trial

* because the trial medicine causes more (serious) side effects than expected, or
* for another reason, which will be explained by the authority involved.

## Will I get a compensation for my participation?

The sponsor pays for the expenses this trial and compensates the trial centre for its conduct. You do not have to pay anything to participate in this trial. You will get compensation for your participation in the trial. The compensation Belgian participants receive as part of this clinical trial is not subject to income tax in Belgium.

[Any form of compensation must be stated here. The sponsor must inform the participants about the following:

* Clearly state the various reasons for compensation even if participants get a lump sum (what is included in the amount?)
* The form of compensation (bank transfer, external supplier, etc.) must be defined, including any alternative options.
* The timing and conditions of the payments.

The sponsor must specify the amount of compensation for each category in the document “compensation for trial participants” if a lump sum is given in the ICF.]

The table below describes what you will be compensated for and what amount(s) you will receive. This compensation will be paid by (bank transfer, external supplier, etc). The payment procedure for your compensation will be started after your final examination. The payment term is approximately X weeks. [Optional] The sponsor asks the participants for receipts. These receipts are collected by the trial staff and sent to the sponsor in encoded form.

[The following table gives various examples of compensation. Delete superfluous lines. If applicable: also describe the compensation for spare subjects and for participants who do not pass screening 1 or 2]

|  |  |
| --- | --- |
| Type of compensation | Amount |
| Compensation for the screening visit | [amount] EUR |
| Compensation if you are a spare participant who is admitted to the trial centre on Day X. The following items are included in this compensation: the screening visit, the morning return on Day X and your stay at the trial centre. | [amount] EUR |
| Compensation if you participate in the entire trialThe following items are included in this compensation: the screening visit, the scheduled returns, your stay at the trial centre and the mandatory contraceptives. | [amount] EUR |
| The trial is an additional burden on your daily life and for compliance with the trial instructions, you will be compensated with the following amount | [amount] EUR |
| Compensation if you are invited for an unplanned follow-up visit | [amount] EUR per unplanned follow-up visit |
| Compensation per 24 hours if your stay is extended due to new available data | [amount] EUR per 24 hours |
| Travel costs, public transport, parking | [amount] EUR per visit, [amount] EUR per km [also state if there is a one-way maximum], reimbursement[amount] EUR for parking or free parking |
| [If applicable:] Meals | [amount] EUR per meal |
| [If not included in the lump sum for participation:] Mandatory contraceptives, mandatory sun cream, mandatory dietary restrictions etc. | Compensation of the actual costs the participant has incurred, fixed amount …. |

If your participation stops early, the compensation may be adjusted pro-rata for the part of the trial you completed.

[Please provide more information here on whether personal data are needed for the compensation. The information should state whether these data will be shared with external suppliers. Participants must always be offered equivalent choices with regard to compensation (e.g. if a participant does not want to have compensation via a charge card, they should be offered the opportunity to receive compensation using a method where no personal data are shared with an external party, e.g. bank transfer/voucher via the trial centre). This option should be clearly outlined in the paragraphs below. Participants should also be asked to confirm their consent via the relevant box in Chapter II.]

[Example: The sponsor has appointed an external supplier who uses a [compensation form via external supplier, e.g. charge card] to compensate you. If the supplier needs personal information from you, they are obliged to process your data in accordance with current European and Belgian legislation (Ref.[[4]](#endnote-4)). This [form of compensation] can be used in various shops. This website contains a list of all the shops where you can use the [form of compensation]: [website].

You can agree or not agree to this form of compensation by ticking the relevant box in Chapter II. If you do not agree, the sponsor will compensate the trial centre. The trial centre will then in turn give you the same amount in compensation as stated above via [form of compensation via the trial centre, e.g. bank transfer/voucher].]

If multiple forms of compensation are possible, add the clause below: You have the right to withdraw your decision on a certain form of compensation at any time for whatever reason, without needing to justify your decision. If you have any problems receiving your compensation, please do not hesitate to contact the trial staff.

## What data will be collected about me during the trial and what will happen to them?

* 1. What data will be collected and processed during the trial?

The collected and processed personal data are about your health and medication condition, including your medical history, a part of your background information (e.g. your age, sex and ethnic background) and the results of the trial tests.

Biological background/race and ethnicity data are collected to make sure trial data are processed in a population as broad as possible.

[If applicable: add a sentence on the collection of other types of personal data, such as biometric data, genetic data, data from third parties.]

Please always comply with the GDPR principles of data minimisation and proportionality.

* 1. How will the investigator handle my personal data?

The investigator (and the trial staff) is bound by professional confidentiality or by a confidentiality agreement when collecting and processing your data.

This means that he/she will never disclose your identity, not even in a scientific publication or presentation, and that he/she will encode your data (Ref.[[5]](#endnote-5)) (i.e. he/she will replace your identity in the trial with an identification code) before sending them to the sponsor. In other words, this code will not contain a personal identifier or combination of identifiers such as your surname, first name, initials, full or partial date of birth, medical file number, etc. [A detailed description of the structure of the identification code must be included in the protocol]

This is why the investigator and the trial staff under the responsibility of the investigator are the only people who can link your identity to the data shared during the trial, apart from those listed under § ‎11.5.

The data the sponsor receives will therefore not enable them to identify you.

* 1. How will my data be processed?

[Information about the legal basis for data processing.]

Your trial data will be processed in accordance with current European and Belgian data protection legislation (Ref.4).

[The sponsor is OBLIGED to choose a legal basis for processing of the encoded data. The choice made has consequences for the sponsor and comes with obligations. The choice must be in accordance with Belgian and European legislation.

There are 4 legal grounds that can be chosen, listed below under a-d. Each legal ground gives participants certain rights and restrictions, which are described in paragraph ‎11.4.]

The reason why we are allowed to process your personal data, is that we are conducting scientific research and that [choose from the following options]

* you **have given your consent**. (a)
* we need to comply with a **legal obligation, specifically** [state the legal obligation, e.g. transfer of data to another competent authority], which [name(s) of controller(s)] is/are subject to. (b)
* we need to perform a task that happens [select:] in the **general interest** [or] to carry out official duties that have been assigned to us, by [name of duty, e.g. advancement of science]. (c)
* we [name of controller with legitimate interest] **have a legitimate interest** because [state the legitimate interest, e.g. quality improvement of a product; comment: this concerns the legitimate interest of the sponsor! In this case, the sponsor cannot be a government body]. (d)

[Within the trial the sponsor may process data on the basis of multiple legal grounds. However, each separate processing activity can only happen on the basis of one legal ground. The sponsor can therefore not process the same data on the basis of multiple legal grounds or change between legal grounds. But the legal basis for collecting personal data to conduct the trial might be legitimate interest, while the legal basis for safety reporting might be legal requirement. It should be clear which legal basis forms the basis for processing what data.

For information,

* The sponsor is the controller for all processing activities performed using the personal data of the participants for the purposes of the trial;
* The centre/hospital conducting the trial is the data processor for the processing activities the centre/hospital performs using the personal data of the participants for the purposes of the trial;
* The centre/hospital conducting the trial separately remains the controller for processing of personal data in the medical records of its patients for the purpose of providing medical care to its patients and for its own university research purposes.]
	1. Do I have access to my data collected and processed during the trial and can I correct them?

You have the right to ask the investigator what data are being collected about you and what they will be used for in this trial.

[Depending on the legal ground chosen in paragraph ‎11.3, choose the rights and restrictions below.

If “Legitimate interest” (d) was chosen as the legal ground, the text in this chapter COULD read as follows:

“You have the right to access and check your personal data, and to ask for correction if you find that they are incorrect. These rights will however be postponed to avoid unblinding this trial. It is not possible to have all your data deleted, to object to processing of your data or to restrict that processing. This is because this could lead to distortedtrial results.”]

You have the right to [choose from the following options]

[The letters behind the options refer to the legal ground described above. If e.g. the legal basis consent (a) was chosen, the sponsor can choose to leave out the options followed by an (a), especially the right to restrict. Be aware that restricting these rights is possible, but it should be justified in the document that these rights make it impossible or significantly more difficult to realise specific goals, and that such deviations are therefore needed to achieve those goals.

Appropriate security measures must guarantee that technical and organisational measures are taken, especially to ensure compliance with the principle of data minimisation. Those measures may include encoding provided that this allows these objectives to be met. When those purposes can be met through further processing that does not allow or no longer allows identification of those involved, then this meets those purposes.

It is highly recommended to contact your Data Protection Officer to enquire about the necessary and appropriate precautions.]

* To get access to these data and to review them (a, b, c, d),
* To have all your data deleted (a, b, c, d),
* To receive the collected personal data (this right is only applicable to the legal ground consent and automated processing – restriction is however not possible here!),
* To ask for correction if they are incorrect (a, b, c, d),
* To restrict processing of your data (a, b, c, d),
* To object processing of your personal data (b, d),
* To withdraw your consent for the processing of your personal data (a). Your personal data collected before your withdrawal will be kept to avoid incorrect interpretation of the trial results [if after withdrawal, b, c or d can be used.].

[If applicable] Your right to [depending on the legal ground, choose from the following options retained by the participant as per the above]

* To get access to these data and to review them (a, b, c, d),
* To have all your data deleted (a, b, c, d),
* To ask for correction if they are incorrect (a, b, c, d),
* To restrict processing of your data (a, b, c, d),
* To object to processing of your personal data (a, b, d),

will be postponed for the following reasons, … [enter why rights are restricted], including to prevent the results of the trial from being interpreted incorrectly (e.g. when there is blind administration of medication). Please ask the investigator when you can get access to your personal data.

[If applicable] It is not possible [choose from the following options in line with those deleted above as rights of the participant]

* To get access to these data and to review them (a, b, c, d),
* To have all your data deleted (a, b, c, d),
* To ask for correction if they are incorrect (a, b, c, d),
* To restrict processing of your data (a, b, c, d),
* To object to processing of your personal data (a, b, d),

for the following reasons, … [enter why rights are restricted], including to prevent the results of the trial from being interpreted incorrectly.

* 1. Who other than the investigator and the trial staff has access to my personal data?

**In order to check the quality of the trial**, it may happen that your uncoded personal data or relevant information from your medical records are inspected by people other than the trial staff. This access occurs under the responsibility of the investigator. These people are bound by professional confidentiality or a confidentiality agreement. This may concern:

* Staff designated by the sponsor (monitors and auditors) and people or organisations that supply services to or collaborate with the sponsor. However, they will never pass on your name and contact details to the sponsor. The monitor ensures that there is continuous quality control throughout the entire course of the trial. The auditor performs a single, independent assessment at a certain time during the course of the trial. They check whether the trial is/was being performed according to the protocol, whether the reported data are reliable and whether the trial is in accordance with applicable laws.
* Inspectors of the competent health authorities worldwide.
* An independent audit group.
* Persons designated by the Ethics Committee.

**If needed for the trial**, encoded trial data can be sent to other countries within and outside the European Union (EU) and be reviewed by:

* Staff (other than the inspectors) of the competent health authorities in Belgium (Federal Agency for Medicines and Health Products, FAMHP) or other countries within and outside the EU,
* The Belgian reviewing Ethics Committee(s),
* External researchers,
* The sponsor of the trial, staff designated by the sponsor and people or organisations that provide services to or collaborate with the sponsor, and/or
* Companies in the group of the sponsor in Belgium and in other countries within and outside the EU.

European regulations and Belgian legislation on data protection set out requirements for data transfer to non-EU countries. The sponsor must always ensure that your coded trial data are protected to an equivalent level when transferred to non-EU countries. If the sponsor enters into a data protection agreement for this purpose, a copy of this agreement can be obtained via the investigator.

You can always contact the investigator for more information about such transfers.

* 1. [optional, only for autologous ATMP studies] Who other than the investigator and the trial staff also has access to my data from this autologous ATMP trial?

This trial tests a medicine for autologous cell therapy (ATMP, *advanced therapy medicinal product*). An ATMP is a product produced using your own cell material, which will only be used as a medicine for you personally . There are specific rules around access to data for this type of trials. The managing physician of the manufacturer producing the ATMP, needs access to some relevant **un**coded data about you. This is necessary to guarantee the quality, safety and traceability of this medicine (Ref.[[6]](#endnote-6)).

* 1. [If applicable:] Remote access to your encoded data

Your coded and uncoded data will be stored in the trial centre in paper files and/or electronic databases. The trial centre uses a validated electronic database to store your trial-specific coded data, to which representatives of the sponsor (i.e. monitors, auditors) have access to check the trial-specific coded data. Appropriate measures have been taken to ensure compliance with data protection standards.

Your uncoded data will only be accessed by representatives of the sponsor at the trial centre (i.e. not remotely) under the responsibility of the investigator and, as stated above, they are bound by professional confidentiality or a confidentiality agreement.

* 1. What will happen to the results of the trial?

A description of this trial will be available on <https://euclinicaltrials.eu/search-for-clinical-trials/?lang=nl>. You can visit this website using the information on the first page of this form. [Choose] Within 1 year of the conclusion of the trial [OR] Within 30 months of the end of the trial [OR] [on date of accepted publication if this is a request for an extension] the website will contain a summary of the results (Ref.[[7]](#endnote-7)).

After conclusion of the trial, a description and the results of the trial may be published in specialised medical journals. A copy of the scientific publication [if applicable:] or a summary understandable to a participant will then be available via the investigator or the trial staff.

This website or these publications will not contain any information that would allow you to be identified.

[If applicable, specifically if the sponsor wishes to use the trial data for the FDA (Ref.[[8]](#endnote-8)):]A description of this clinical trial is given on <https://www.ClinicalTrials.gov> as required by United States legislation. The website will not contain information that will lead to you as a person. The website may nevertheless contain a summary of the results. You can consult this website at any time.

[For blind studies: If you want, you can contact the trial centre after your participation in the trial to ask which medicine [trial medicine or placebo] you received. Only for double-blind studies: Please be aware that the trial centre can only provide this information after the results of the trial have been processed by the sponsor. This will be within 1 year of the conclusion of the trial.]

* 1. Will my data be used for purposes other than the trial I am participating in?

[Choose:]

The results of the trial will only be used to answer the scientific questions in this trial.

[or]

 The results of the trial will be used to answer the scientific questions of this trial. Moreover, the sponsor would like to use your data from this trial in other research and development activities (and scientific publications linked to those). These activities can only be about:

* The efficacy of [name of the trial medicine] and similar medicines,
* The same disease/condition [name of the trial medicine] is being tested for in this trial, or
* Other diseases and health problems for which [name of the trial medicine] could offer a solution, or related diagnostic tests (simple tests that help to determine what is going on).

Any additional or future research outside the trial that has therefore not been described in the points above, must always be approved by an accredited Belgian Ethics Committee.

[When the processing for a purpose other than the purpose the personal data were collected for is not based on the participant's consent or on EU legislation or legislation in another Member State, the sponsor should consider the below to verify whether processing for that other purpose is consistent with the purpose for which the personal data were initially collected:

(a) any relationship between the purposes for which the personal data were collected and the purposes of the intended further processing;

(b) the context within which the personal data were collected, in particular considering the relationship between the participant and the sponsor;

(c) the nature of the personal data, especially whether special categories of personal data are being processed in accordance with Article 9 of the GDPR, or that personal data are being processed in relation to criminal convictions and offences, in accordance with Article 10 of the GDPR;

(d) the possible consequences of the intended further processing for those involved;

(e) the existence of appropriate security measures, including encryption or encoding.

It is highly recommended to contact your Data Protection Officer to enquire about this compatibility and to decide whether consent is the legal basis that will be chosen for the processing in these other research and development activities and whether the following sentence should be included. For more information, consult GDPR Articles 5, 6 and 89.]

[If applicable and if “consent” was chosen as the legal ground for data processing] You can agree or not agree with the use of your trial data for other purposes outside the context of the trial by ticking the relevant box in Chapter II.]

* 1. How long will my data be stored?

At the end of the trial, your encoded data will be stored for at least 25 years (Ref.[[9]](#endnote-9)) to guarantee the validity of the trial. That will also be the case if you end your participation in the trial early.

## What biological samples will be collected from me during the trial and what will happen to them?

* 1. What biological samples will be collected from me during the trial?

Biological samples are samples of human bodily material.

In this trial, the following biological sample(s) will be collected: [specify briefly]

A coding procedure will be used for these samples as for your personal data (see I § ‎11.3 Ref.[[10]](#endnote-10)). When samples are sent to the sponsor, or to organisations collaborating with the sponsor, they will only be able to see your identification code. The sponsor makes sure that the location of your biological samples will always be tracked. The use of your biological samples is related to the processing of the corresponding coded personal data.

Your biological samples are a donation. You will not receive any financial benefit associated with the development of new therapies derived from the use of your biological samples and which may be of commercial value.

* 1. What happens to the collected biological samples within the context of the trial?

These biological samples will be analysed for the purposes of this trial.

[If remainders of samples are **destroyed**, include the following text:] Your biological samples will be destroyed after the analyses for this trial have been completed.

[If samples are stored as part of the trial, add the following passage:]

As science in this field is continuously advancing, the sponsor would like to keep the remainders of your biological samples for another [number] years. The sponsor does this for additional research that remains within the context of the current clinical trial and is therefore about the same disease or about the same treatment/medicine as this trial.

[If storage of samples for use in additional research within the context of the trial is optional:] You can either agree or not agree to the storage of the remainders of your biological samples for additional research within the context of this clinical trial by ticking the relevant box in Chapter II.

[If additional samples are collected as part of the trial, add the following passage:]

With your consent, the sponsor would also like to invite you to participate in additional research that remains within the context of the current clinical trial and is therefore about the same disease or about the same treatment/medicine as this trial.

Your participation in this additional research is optional and involves donating additional biological samples. These biological samples will be stored for [number] years. This concerns the following biological samples: [list the additional biological samples that will be collected].

[Choose:] More information about this additional research is given in Chapter [number], part [number]. You can either agree or not agree to donate additional biological samples and to participate in the research described by ticking the relevant box in Chapter II.

[or]

We will give you more information about this research in a separate informed consent form. If you want to participate in this additional research, we ask you to sign this separate form.

[If any genetic testing is performed as part of the trial, add the following passage:]

[Choose:]

Genetic analyses will also be performed on your biological samples. Genetic analyses involve testing your DNA. For example, DNA determines the colour of our hair and our eyes. DNA may also explain why some people respond to certain medicines and others do not. It may also explain why some people get certain disease and others do not. The purpose of the genetic analyses in this trial is … [Explain the purpose].

These genetic analyses generate essential information for the trial. If you do not want these analyses to be performed, you cannot participate in the trial.

[or]

You can agree or not agree to genetic analyses being performed on your biological samples by ticking the relevant box in Chapter II.

* 1. Will biological samples be used for research outside the context of this trial?

[If no additional biological samples are collected and the remainders of the biological samples are destroyed or only used within the context of the trial, this chapter ‎12.3 can be deleted.]

[Please note: biological samples under this paragraph must be registered in an accredited Belgian Biobank.]

[In case of secondary use of samples, i.e. for additional research not about the same disease or about the same treatment/medicine as in this trial, add the following passage:]

[If **remaiders of** biological samples are used for additional research outside the context of this trial, add the following sentence:]

You can agree or not agree to the sponsor storing the **remainders** of your biological samples for [number] years for additional research outside the context of this trial by ticking the relevant box in Chapter II.

[If **additional** biological samples are being collected for additional research outside the context of this trial, add the following sentence:]

You can agree or not agree to give **additional** biological samples and to these samples being stored for [number] years for future research outside the context of this trial by ticking the relevant box in Chapter II.

If you agree, this future research is only permitted if it is conducted in accordance with legislation on the use of human tissue (Ref.[[11]](#endnote-11)) and with the approval of an accredited Belgian Ethics Committee.

[If any genetic testing is performed outside the context of the trial, add the following passage:]

You can agree or not agree to genetic analyses being performed on your biological samples outside the context of this trial by ticking the relevant box in Chapter II. The purpose of these analyses is … [Explain the purpose].

[If the additional biological samples or the remainders of the biological samples are intended to produce/obtain artificial or extracted material only for non-genetic research outside the context of this trial, add the following passage.]

If you agree, the sponsor would like to create or culture material with your additional biological samples or remainders of your biological samples (e.g. cell lines or cell cultures: letting cells grow and divide under controlled conditions outside the body) or obtain material from it that does not contain cells (e.g. proteins) and use this material for non-genetic research outside of the context of this trial only. In that case, the sponsor will break the link between your biological samples and your identity, as explained below in §‎12.4.

You can agree or not agree to material from your additional biological samples or remainders of your biological samples being created/cultured or obtained exclusively for non-genetic research outside the context of this trial by ticking the relevant box in Chapter II.

[If the traceability of the biological samples is due to be erased, add the following passage. Erasure of traceability of biological samples is only possible with the explicit consent of the donor.]

* 1. May the link between my biological samples and my identity be broken?

If you agree to this, it will no longer be possible to link your biological samples to your identity after they have been used in the context of this trial.

This will mean that it will not be possible to inform you of possibly meaningful information obtained from analyses on your samples.

You will also no longer be able to withdraw your consent for the use of your samples or ask for your samples to be destroyed.

You can agree or not agree to your biological samples no longer being linked to your identity after use within the context of this trial by ticking the relevant box in Chapter II.

## What if research generates meaningful information about your health?

It is possible that we discover new information about your health. If this information could be of interest to your health, the sponsor will inform the investigator. With your consent, the investigator will inform you and your GP about your results and the possible consequences. If needed, the investigator and/or your GP will advise on what you should do.

You can inform the investigator whether you agree or do not agree to being informed about meaningful information about your health by ticking the relevant box in Chapter II. The investigator/your GP will in any event give you this information if not telling you would be very unfavourable for your health and/or others’ health.

## Who has reviewed and approved the trial documents?

The trial documents have been reviewed by:

* The Belgian competent health authorities (FAMHP) or if applicable, by the national competent health authorities of other EU Member States, and
* An independent Belgian Ethics Committee

The competent health authorities and Ethics Committees are charged with protecting people who participate in a trial. The competent health authorities will ensure that the trial is performed in accordance with applicable legislation.

You should not consider their approval to be an incentive to participate in the trial.

Screening number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# CHAPTER II - INFORMED CONSENT

*The official lay trial title as given in the CTIS database*

[General comment for the sponsor: This part can only contain information already stated in the previous parts of this document.]

## Participant

[Limit this part to maximum 3 pages.]

REQUIREMENTS FOR YOUR PARTICIPATION IN THE TRIAL

* I declare that I have read this form and that I have understood the information it contains.
* I declare that I have been informed about the purpose, duration and the consequences of the trial, the possible risks and discomforts, the precautions I need to take and what is expected of me, and that I have understood all of this. My rights as a participant in a trial have been explained to me and I have understood them.
* I have had sufficient time to think about it and to talk about it with a trusted person (e.g. friends, family, GP, ...).
* I have been given the opportunity to ask any questions that came to mind and have obtained satisfactory answers.
* I understand that I will voluntarily participate in this trial without having been forced to and that I can stop my participation in the trial at any time.
* I understand that data will be collected about me and that these data will be treated as confidential as described in Chapter I, § ‎11.2.
* [If “consent” is chosen as the legal basis, use:] I agree to my personal data being processed as described in Chapter I, § ‎11.
* I understand that representatives of the sponsor, the Ethics Committee and competent health authorities will have access to my medical records for this trial if they are authorised to this (as described in Chapter I, § ‎11.5).
* I understand that the sponsor has taken out insurance in the event I should suffer damage as a result of my participation in this trial.
* I understand that I will not incur any costs if I participate in this trial.
* I understand that my GP and other specialists involved in my health may be informed of my participation in this clinical trial.
* If I participate in another clinical trial, I must let the investigator or the trial staff know. I agree that I will not participate in another clinical trial (e.g. with a trial medicine, medical device, experimental surgical technique) at the same time without informing the investigator or the trial staff about this and that participation may be refused for justified reasons.
* I understand that I need to cooperate and that I need to follow the instructions of the investigator and of the trial staff regarding the trial.
* I understand that my participation in the trial may be terminated without my consent if I need another treatment, do not follow the trial schedule, have an injury related to the trial or for whatever other justified reason.
* [In the event of mandatory genetic analyses] I understand that genetic analyses will be done on my biological samples.
* I confirm that all the information I have given about my medical history is correct. I understand that I may be harmed if I fail to inform the trial doctor about or fail to point out possible exclusion criteria (reasons to not let me participate in the trial).
* I understand that my samples will be used as explained in this form.

OPTIONAL CONSENT THAT IS NOT AN ABSOLUTE REQUIREMENT FOR YOUR PARTICIPATION IN THIS TRIAL

**Compensation VIA AN EXTERNAL SUPPLIER**

1. [If compensation via an external supplier may be arranged and personal data are collected for this] As mentioned in Chapter I, § ‎10, it is possible for you to receive your compensation via [form of compensation via external supplier, e.g. debit card] and an external supplier, named [external supplier], will need to process certain personal data from you. If you do not agree to share your personal data and/or receive the compensation via this form of compensation, the sponsor will compensate the trial centre. The trial centre will then in turn give you the same amount in compensation as stated above via [form of compensation via the trial centre, e.g. bank transfer/voucher].

Do you agree to your personal data being shared with an external supplier [external supplier] to pay out your compensation via [form of compensation, e.g. debit card]?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

**TRIAL data**

1. [If applicable and if “consent” was chosen as the legal ground for data processing] As stated in Chapter I, § ‎11.9, the sponsor would like to use your trial data for other research and development activities (and scientific publications linked to those). These research purposes must be approved by an accredited Belgian Ethics Committee.

Do you agree to your data obtained in this trial being used for other research purposes outside the context of the trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

**BIOLOGICAL SAMPLES WITHIN THE CONTEXT OF THE TRIAL**

1. [If optional genetic analyses are planned within the current trial protocol] As mentioned in Chapter I, § ‎12.2, the sponsor would like to perform genetic analyses on your biological samples within the context of the trial you are due to participate in.

Do you agree to the sponsor performing genetic analyses on your biological samples within the context of the trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

1. [If storage of remainders of biological samples for use in additional research within the context of the trial is optional] As mentioned in Chapter I, § ‎12.2 the sponsor would like to store the remainders of your biological samples for [number] years for future research within the context of the trial you are due to participate in. Do you agree with the retention of the remainders of your biological samples for future research within the context of the trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

1. [If applicable] As mentioned in Chapter I, § ‎12.2 the sponsor would like to take additional biological samples from you and store these samples for [number] years for future research within the context of the trial you are due to participate in.

Do you agree to your additional biological samples being stored for future research within the context of the trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

**BIOLOGICAL SAMPLES OUTSIDE THE CONTEXT OF THE TRIAL**

1. [If applicable] As mentioned in Chapter I, § ‎12.2 the sponsor would like to store the remainders of your biological samples for [number] years for future research outside the context of the trial you are due to participate in.

Do you agree with the retention of the remainders of your biological samples and the corresponding personal data for future research outside the context of the trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

1. [If applicable] As mentioned in Chapter I, § ‎12.3 the sponsor would like to take additional biological samples from you and store these samples for [number] years for future research outside the context of the trial you are due to participate in.

Do you agree to your additional biological samples being stored for future research outside the context of the trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

1. [If applicable] As mentioned in Chapter I, § ‎12.3, the sponsor would like to perform genetic analyses on your biological samples outside the context of the trial you are due to participate in.

Do you agree to the sponsor performing genetic analyses on your biological samples outside the context of the trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

1. [If applicable] As mentioned in Chapter I, § ‎12.3 the sponsor would like to create or culture material from your additional biological samples or the remainders of your biological samples (e.g. cell lines or cell cultures) or obtain material from it that does not contain cells (e.g. proteins) and use this material for non-genetic research outside of the context of this trial only.

Do you agree to material from your additional biological samples or the remainders of your biological samples being created, cultured or obtained exclusively for non-genetic research outside the context of this trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

**BREAKING THE LINK BETWEEN BIOLOGICAL SAMPLES AND IDENTITY**

1. [If applicable] As mentioned in Chapter I, § ‎12.4 the sponsor would like to break the link between your biological samples and your identity after use of your biological samples in the context of this trial.

Do you agree to it being no longer possible to link your biological samples to your identity after they have been used in the context of this trial?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “I do not agree”.)**

|  |  |
| --- | --- |
| **☐ I agree**  | **☐ I do not agree**  |

**MEANINGFUL INFORMATION**

1. As described in Chapter I, § ‎13 meaningful information may be found that could be important for your and/or others’ health.

If this happens, do you want the investigator/your GP to inform you about this result?

**(Tick the box of your choice; if you do not tick a box, we will assume that your answer is “Yes, I want to be informed”.)**

|  |  |
| --- | --- |
| **☐ No, I do not want to be informed**  | **☐ Yes, I want to be informed** |

I agree to participate in the trial, [if the participant needs to answer optional questions:] with the restrictions above, and I have received a signed and dated copy of the informed consent form plus all the pages of this document.

Surname and first name of the participant:

Date (DD/MMM/YYYY):

[If screening and randomisation happens on the same day] Time:

Signature of the participant:

## [If a witness is present.] Impartial witness (Ref.[[12]](#endnote-12))

I, the undersigned, was present throughout the entire informed consent procedure and confirm that the information about the purposes and procedures of the trial was adequately provided. I confirm that the participant has in all likelihood understood the trial and that consent was given out of free will.

Moreover, I declare that, acting as an impartial witness, I do not have any ties with the sponsor and the investigator.

Surname and first name of the impartial witness:

Capacity of the impartial witness:

Date (DD/MMM/YYYY):

[If screening and randomisation happen on the same day] Time:

Signature of the impartial witness:

## Investigator

[The investigator is the physician or dentist who held or supervised the discussion with the participant. This may possibly not be the principal investigator of the trial centre. If another member of the trial staff also participates in the discussion with the participant, this person must also sign the ICF as a delegate. In any event, the investigator always signs last.]

I, the undersigned investigator, confirm

* That the participant has received the necessary verbal information about the trial, that the contents have been explained to him/her and that he/she has received an original signed version of this document.
* That I have verified whether the participant has understood the trial.
* That I have given the participant sufficient time to think about his/her participation and to ask questions.
* That the participant was not pressured in any way to make him/her agree to participate in the trial.
* That I operate in accordance with the ethical principles set out in the most recent version of the “Declaration of Helsinki”, “Good Clinical Practice” and the Belgian Law (Ref.[[13]](#endnote-13)).

[Optional signature of a delegate]

Name and surname of the delegate of the investigator:

Capacity of the delegate of the investigator:

Date (DD/MMM/YYYY):

[If screening and randomisation happen on the same day] Time:

Signature of the delegate of the investigator:

[Mandatory signature of the investigator]

Surname and first name of the investigator:

Date (DD/MMM/YYYY):

[If screening and randomisation happen on the same day] Time:

Signature of the investigator:

# REFERENCES

1. The definition of an interventional study is available in the European Commission Q&A document (draft version), which is available in Eudralex Volume 10, Chapter V, accessible via the following link: https://ec.europa.eu/health/documents/eudralex/vol-10\_en#fragment1. [↑](#endnote-ref-1)
2. In accordance with Article 74 of Regulation 536/2014 and Article 12, §2 of the Belgian Law of 7 May 2017 on clinical studies for human medicines, the sponsor or a legal representative of the sponsor must be based in the European Union. [↑](#endnote-ref-2)
3. This is in accordance with Article 12 of the Belgian law of 7 May 2017 on clinical studies for human medicines and the applicable Royal Decrees. [↑](#endnote-ref-3)
4. General Data Protection Regulation No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

Belgian Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data. [↑](#endnote-ref-4)
5. Throughout the document, the term “encoding” is used as a synonym of the term “pseudonymising”, the term used in General Data Protection Regulation No. 2016/679. [↑](#endnote-ref-5)
6. Belgian Law of 19 December 2008 on obtaining and using human tissue with a view to using it for medical application on humans or scientific research and the relevant Royal Decrees. [↑](#endnote-ref-6)
7. In accordance with Chapter 4.3. of the Commission Guideline: Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No. 726/2004 and Article 41(2) of Regulation (EC) No. 1901/2006 - 2012/302/03. [↑](#endnote-ref-7)
8. If the sponsor wishes to use the data for the FDA, this sentence must be included in the ICF (CFR 50.25(c)) as described in the following guidance (<https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm291085.pdf>). [↑](#endnote-ref-8)
9. In accordance with Article 58 of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. [↑](#endnote-ref-9)
10. Belgian Law of 19 December 2008 on obtaining and using human tissue with a view to using it for medical application on humans or scientific research and the relevant Royal Decrees. [↑](#endnote-ref-10)
11. This is in accordance with Article 21 of the Belgian Law of 19 December 2008 on obtaining and using human tissue with a view to using it for medical application on humans or scientific research and the relevant Royal Decrees. [↑](#endnote-ref-11)
12. An impartial witness must be used when the participant or their legal representative speaks and/or fully understands the language of the approved informed consent form but cannot read and write as a result of a physical or visual handicap. [↑](#endnote-ref-12)
13. Belgian law of 7 May 2017 on clinical studies for human medicines and the applicable Royal Decrees. [↑](#endnote-ref-13)