MODEL ICF FOR INTERVENTIONAL CLINICAL TRIALS WITH IMP ON ADULT PATIENTS

GUIDANCE

The intention of the template and how to use it

This template is intended to prepare an informed consent form (ICF) for adult patients participating in an interventional (Ref. 1) clinical trial (further on referred to as “trial”). (In the Dutch and French templates the terms “klinische studie / studie” or “étude clinique / étude” have been used instead of the legal terms “klinische proef / proef” or “essai clinique / essai” which is less known to lay persons.)

The following color codes are used:

- in purple: the text is mandatory and may only be adapted with a justified reason. The sponsor must add to the submission file a statement which describes which version of the ICF template was used, and (if applicable) which changes were made to the purple text and for which reason. A template for this statement is available on the website of the CT-College (documents/sponsor-statement-template).
- In black: the text is a proposal and can be adapted in function of the needs of the trial
- in blue: the text must be replaced by trial specific information.
- in red: the text contains guidance for the sponsor on how to complete the section. This text must be removed together with this guidance part of the document.

The footer of the document can be adapted according to the sponsor’s preferences.

The template contains “fields” and “cross-references” which in MS-WORD may be updated using F9 or right-click and select Update Field. (To update all references in a document, select Select All (in MS-Word press Ctrl A), then press F9.)

Editorial recommendations

The ICF must be written in a **language that is clear and understandable** for the participant. The document must be worded such that it can be read and understood by people who are not health-care professionals and who have not received any oral explanation. The text should be understandable for people with an educational level of a 12 year old.

Please take note of the following advices:

a. Use the correct sentence structure (pay attention to problems of literal translation from English to French/Dutch, inappropriate choice of terms, etc.).

b. Use short sentences (less than 12 words) and short paragraphs (less than 7 lines). Use bullet points where possible.

c. Avoid technical jargon.

d. If a reference to another chapter is included, the reference should also include the page number of this chapter.

e. For the same concept use the same terminology throughout the whole document. Examples: In this template the following terms are used:

   - "Clinical trial" or "trial" (instead of research, study, …)
   - "Trial staff" (instead of investigating team, staff, trial team, …)
   - "Investigator" for the health care professional in charge of the trial
   - "Treating physicians" for all other medical doctors in charge of the treatment of the participant
   - The term "Hospital "is used in this document for patient studies, which is not always correct for studies performed at a private practice location. In the latter case the word "Hospital" refers to the location of this particular trial.
   - Depending on the situation, in the template the term "comparator" can be read as "the standard treatment" in case of a combined therapy.
   - In the purple text of the template the more common term "encoding" is used instead of the term "pseudonymizing". To avoid any confusion, it is advised to use this term also in the trial specific parts of the text.
   - In the template the term "emergency card" is used. This shouldn't prevent the sponsor to replace it with another sponsor specific term.
   - In the French template the expression « devenir enceinte » is used instead of « tomber enceinte ». It is advised to use these terms also in the trial specific parts of the French text.

f. Avoid the over-use of abbreviations and if necessary explain the abbreviations in glossary. Display in capital letters in the text the terms or abbreviations that are explained in the glossary. To introduce an abbreviation, write out the full terminology followed by the abbreviation between brackets the first time it appears in the text.

g. Use a clear and sufficiently large font size:

   - when printing on A4 in one or two columns, preferably use a font size ≥ Arial 12;
   - when printing in booklet format, the margins should be reduced and the font size increased to ≥ Arial 16.

h. Use an attractive design with sufficient subtitles and white rules.

i. If possible, involve a patient or patient association in the development of the ICF (in relation to comprehensibility, relevance of information).

j. All pages of the document should be identified by the same version number of the ICF and the same date of issue.

k. The pagination of the whole document will be presented in the format “page X/Y”. Where Y indicates the total number of pages.

For the Dutch ICFs we refer you to the information documents “Schrijfadviezen voor de geneesmiddelenbijsluiter” (Universiteit Utrecht) and “Patiëntvriendelijke termen” of the Dutch “College ter Beoordeling van Geneesmiddelen (CBG)” which can be found via the following link: https://www.cbg-meb.nl/onderwerpen/hv-patientenbijsluiter.

For the French ICF we refer you to FALC, FAcile à Lire et à Comprendre: https://www.falc.be/.

Front Pages

The front page of the template mentions the minimal requirements of information to be indicated on the ICF front pages. The sponsor is allowed to add information. It is however not allowed to add the contact details of the Data Protection Officer of the sponsor. (The sponsor does not know the participant and thus cannot inform him/her of his/her rights.)

Regarding the contact details: except for the name and contact details of the insurance company of the sponsor and the contact details of the Belgian Data Protection Authority, all contact details are site specific and will be completed after the ICF is approved by the Ethics Committee.

The phone number mentioned for the “Emergency contact” should be a number directed to the site staff 24h/7days and who can help the patient in his/her own language with urgent health related questions. This should not be the phone number of the hospital emergency department.

It is possible that no Data Protection Officer (DPO) or patient rights ombudsman is available at the trial site, for example for trials in private practices. Only in those specific cases :

- The “Data protection officer of the site” can be replaced by the “Principal Investigator of the site” that will take on the role of DPO.
- The “patient rights ombudsman” can be replaced by the FAMHP or the CT-College depending on the type of trial:

Studies submitted via a pathway or procedure where the CT-College is involved, e.g. submitted under CTR Pilot, or CTR: The “patient rights ombudsman” can be replaced by “Clinical Trial College”	e-mail: ct.college@health.fgov.be
Studies submitted via a pathway or procedure where the CT-College is not involved, e.g. submitted under - CTD	e-mail: inspection @fagg-afmps.be

The “patient rights ombudsman” can be replaced by “Federal Agency for medicines and health products (FAMHP)”	

The ICF template version 1.0 was adopted by the Workgroup on Informed Consent Form on 27/06/2019.

This working group consisted of representatives of BAREC (Belgian Association of Research Ethics Committees), pharma.be *(*the *Belgian association of the innovative (bio)pharmaceutical industry) and patient organizations, and was coordinated by the* CT-College *at the* FPS Health Food *chain safety* and Environment*.*

The Belgian Data Protection Authority (DPA) has been asked for advice on the GDPR aspects in this template on 28/06/2019.

The GDPR working group of the RUZB/CHAB has accepted the GDPR aspects in this template at the meeting of 18/02/2019.

Version 1.1 contains decisions taken by the Board of the College and some minor adaptations. The adaptations compared to version 1.0 are highlighted in yellow.

TEMPLATE

[FRONT PAGES]

Official lay title of the trial as given in the EUDRACT data base

Official title of the trial: *Official title*

EU number: *Official EUDRACT number or EU CT number*

Trial number: *Sponsor trial number*

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

[If applicable:] European representative: *name and address of European representative*

[If applicable] Contract Research organisation*: Name and address of CRO*

Site name: *official name of site [as available on the website of the FPS Health, Food chain safety and Environment (FR,NL)]*

Main address of site: *address of site*

[Optional] Site number: *add site accreditation number*

[If a new version of the ICF is prepared, insert a Document Revision History table to inform the participant of the essential changes. This revision table is useful for both the Ethics Committee(s) and the participant. An example is given below.]

[If applicable:] ***Document Revision History***

Version No.	Version Date	Revision description
2.0	dd-mm-yyyy	e.g. I.4.1 additional side effects included
3.0	dd-mm-yyyy	e.g. I.8. changes due to new legislation

Who can I contact in case of questions?

Name	Function	In case of	Contact details
Surname, First name	Principal Investigator of the site	Information, problems or concerns	Phone N°, E-mail
	The trial staff	Information, problems, concerns	Phone N°
	Emergency contact [not emergency department of hospital]	Emergency	Phone N°
	Patient rights ombudsman	Concerns relating to your rights as a participant in a trial	Phone N°
Name and address of insurance company of the sponsor & contact of insurer	Insurance Company of the sponsor	In case of disagreement or complaint on a damage claim	Policy N°
	Data protection officer of the **site**	Questions relating to the confidentiality of your data	Phone N° E-mail: e-mail
	Belgian Data Protection Authority	Complaints relating to the confidentiality of your data	E-mail : contact@apd-gba.be

Version No: *Version No of the ICF* [Mention the version No in the footer of the final ICF since it has to appear on each page of the document.]

Table of contents

THE TRIAL AT A GLANCE

Please briefly describe in this chapter, (maximum 2-3 pages), an answer to the following questions:

1. Why is the participant being asked to take part? What is the purpose of the trial? Include the disease of the participant, and if applicable, his/her limited life-expectancy.
2. What is the purpose of this document?
3. Will the participant benefit from the trial?
4. How will the IMP be administered?
5. Which most significant/painful examinations will be conducted?
6. What is the duration of the trial?
7. Will the IMP produce side effects?
8. Is there an insurance cover in case something goes wrong within the trial?
9. Can the participant (or his/her partner) get pregnant during the trial?
10. Who pays trial specific costs and what does the participant have to pay or not?
11. Inform the participant if personal data are processed and whether the data are treated confidentially?
12. Is the participant free to take part?
13. Who has reviewed and approved the trial documents?
14. Will the participant receive the IMP after his/her participation in the trial?
15. Which commitments are expected from the participant? Please incorporate the commitments:
    - to agree that the investigator informs the treating physicians regarding participation in the trial
    - not to take part in any other clinical trial at the same time
    - to communicate the relevant information related to the state of health, other medication taken or the symptoms experienced
    - to carry the "emergency card" at all times
16. Who can give more information to the participant?

Use very simple words, to ensure that everyone understands these 2-3 pages.

An example of this chapter is available through the following link: example-EN

The sponsor can check the readability of this chapter using the following tools:

For French, English: https://labs.translated.net/lisibilite-texte/

For Dutch, English: https://www.lt3.ugent.be/readability-demo/

CHAPTER I – DESCRIPTION OF THE TRIAL AND YOUR RIGHTS WHEN PARTICIPATING

1. Why are we doing this trial

[Please specify in this section the IMP(s), *i.e.* name of tested trial drug(s), and name of comparator(s).]

This clinical trial (further on referred to as "trial") will evaluate the investigational medicinal product (IMP), [name of IMPs] for the treatment of [name of disease/condition]. The purpose of this trial is to learn about : [add the objectives of the trial; specifying the mode of action of the IMP(s), the number of patients that have already received this IMP for this and/or for any other indication, …]

2. Why am I being asked to take part?

You have been diagnosed with [name of disease/condition].

You are being asked to take part in this trial because

[Add a brief description of the main inclusion/exclusion criteria as set out in the protocol and which the participant is able to understand.]

[Choose:]

[If an alternative treatment is available:] For your disease/condition, the following alternative treatments are available, other than taking part in the trial: …

[OR]

[If no alternative treatment is available:] For your disease/condition, no treatment is currently available in Belgium that has been approved by the authorities,.

[If life expectancy is limited, this information should be included as well, e.g. :] You have [name of disease/condition] and for your condition the standard treatments aiming at improving survival have not worked. This means your life-expectancy is limited. It is not guaranteed that your participation in this trial will cure your disease/condition, improve your quality of life, or will extend your life.

The investigator or trial staff will discuss with you the requirements to be allowed to enter the trial.

3. Do I have to take part in a trial?

Your participation in a trial is voluntary and must remain free of any coercion. This means that you have the right not to take part in the trial or to withdraw at any time

without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the investigator or your treating physician nor will it affect the quality of your future medical care.

If other treatments are available for your disease/condition, the investigator or his/her delegate will discuss these treatments with you. It could concern the following treatments: [add other treatments]

4. What will happen during the trial?

[Please note that it is not acceptable to add to this section (or elsewhere) any text which could intimidate or influence the participant (not) to stop taking part in the trial, such as "the sponsor can track you down if you decide to end your trial participation…" or "we can use whatever means to track you down ……" etc.]

This trial will include about [number] participants worldwide, including about [number] in Belgium.

This trial is a …

[Add a brief description of

- the trial design in terms understandable to the participant: e.g.: explain randomised/blind/cross-over trial/placebo/screening, comparing the IMP(s) with the placebo and/ or comparator. If applicable, add information on the probability of the random assignment of the treatment.
- the dose, the method and frequency of administration, number of visits.
- the course of the trial: screening phase (including duration), trial phase (when to be started, start of the dosing of the IMPs, comparator, placebo in the trial phase), premature or planned withdrawal from the trial, follow-up phase.
- the scheduled examinations (incl. the time spent by the participant) and any precautions to be taken before undergoing these examinations.

It may be useful to provide the participant with a detailed plan or flow chart of the various examinations he/she will be required to undergo at each of the scheduled visits. If a flow chart is provided also include some guidance on how it should be interpreted.

No matter how the information is provided (via text or flow chart), the sponsor should indicate in an annex (referred to in section I § 11) which visits, treatments and examinations are specific to the trial and are therefore charged to the sponsor. This can be done by using a superscript (e.g. TS) or by putting these items in bold. The sponsor can provide this information in the ICF using one of the following approaches:

- The list of treatments/examinations/visits is added to the current section without indicating the trial specific ones. The same list should then be copied to the annex, which is handled as described in section I § 11.

- The list of treatments/examinations/visits is given only in the annex and a reference to it is added to the current section. The annex is handled as described in section I § 11.]

Overall, your participation in the trial will last [choose] about [number] weeks/months and involve [number] visits [or] according to your health status.

If you meet all the conditions required to be enrolled in the trial and agree to take part in the trial, you will undergo the above-mentioned tests and examinations. If you have any important side effects, the investigator might determine that it is necessary to perform additional tests which will be considered as specific to the trial.

[In case of self-medication by the participant:] We expect that you will use [name of IMP/comparator] as described above.

5. Will I benefit from the trial?

The information obtained during a trial may contribute to a better understanding of the use of the investigational medicinal product (referred to as "IMP") or to the development of a new medicinal product for the treatment of yourself or future patients.

The IMP may or may not be beneficial in treating your disease/condition or relieving your symptoms. Even if it is beneficial to you, a potential return or worsening of symptoms, illness or disease is still possible.

6. What are the possible risks and discomforts of taking part?

6.1. What are the possible side effects of [name of IMP(s)] [if applicable:] and [name of comparator(s)]?

Participation in a trial involves some risk.

[Choose between the following statements:]

All medicinal products can have side effects. Some of these side effects are already known, and some are not known. Even if previous studies have shown that [name of IMP(s)/comparator] was/were normally well tolerated, you may still experience the following side effects:

[OR]

All medicinal products can have side effects. In view of the benefit/risk balance, previous studies have found that the side effects of [name of IMP(s)/comparator] were acceptable. However, you must be aware that you may experience the following side effects:

[Per IMP/comparator: Add a list of the side effects and describe them briefly. Mention side effects in the order of frequency. Put irreversible side effects (if any) in bold.]

[The notions of frequency of side effects should be quantified in a way that is understandable to the participant: e.g.

Very Common	In more than 1 in 10 patients
Common	Between 1 in 100 and 1 in 10 patients
Less common	Between 1 in 1,000 and 1 in 100 patients
Rare	Between 1 in 10,000 and 1 in 1,000 patients
Very Rare	Between 1 in 100,000 and 1 in 10,000 patients

[If there are certain risks of which the participant should be familiar (including associated symptoms) to be able to take swift corrective action, they can be described here in an additional paragraph; e.g. symptoms of a severe allergy to the IMP.]

[For "add-on therapy" trials, either a brief reminder of the side effects of the standard treatment or a reference to the notice of the standard medicinal product should be provided, or the trial staff provides an adapted version of this notice to the participant together with this ICF.]

Because this IMP is still under investigation, other currently unknown risks and discomforts could occur. **Therefore, it is very important that you report any new or worsened health problems immediately to the investigator, regardless of whether or not you think it has to do with the trial (or to [name of IMP/comparator]), and even when it is already described in this document. If you need to use other medication, discuss this with the investigator before taking it. If, for any reason, you consult another treating physician during the trial you must inform him/her that you are taking part in a trial and present your emergency card. This could be important in determining a diagnosis and giving you the correct treatment if needed.**

[If applicable: Add a section on

- what care the participant may expect if he experiences side effects from the IMP/comparator.
- what happens if the participant does not benefit from the IMP/comparator

6.2. What are the possible risks or discomforts of the examinations during the trial?

[Choose between the following two options:]

There are no known risks of the examinations during the trial.

[OR]

The examinations of the trial may cause the following discomforts and risks: ….

[Add the most important risks/discomforts associated with the specific examinations that will be performed in connection with the trial.

[For studies involving the taking of blood samples] The **taking of blood** (around [number] ml of blood, [or] [number] of tubes of blood) necessary for analysis of … [to be completed] may cause pain, bleeding, bruising or infection localised around the injection site. Similarly, some participants may feel dizzy or even faint during the procedure. The staff who take the blood will do all they can to minimize these discomforts.

[Add risks, discomforts, precautions to be taken (e.g. not driving a car) associated with e.g. X-ray, MRI, Biopsy, etc. Specify the additional radiation dose of the examinations compared to the natural background radiation and the risks associated with this additional radiation dose. Please use as a reference the text approved by the FANC to be retrieved via http://belnuc.be/nm-physicians/. This text will become available as soon as BELNUC board members will have approved it.]

6.3. Can I take other medicines during the trial?

[If applicable: Present the relevant information relating to warnings, interactions, precautions or contraindications associated with the use of the IMP(s)/comparator.]

Do not hesitate to ask your investigator for more explanation about the use of other medicines and food supplements.

6.4. Will my participation to the trial have an impact on my daily activities?

[If applicable: Describe here the extra patient burden: deviations from daily life or life style restrictions (e.g. it is not allowed to travel, exercise, use alcohol or tobacco, certain foods, drinks, …). This is important for chronic patients.]

6.5. [optional] Can my partner or I get pregnant or can I breastfeed during the trial?

- For a woman taking part in the trial, it is easy to understand that exposing the developing foetus to the medicinal product could constitute a risk for the unborn child.

  For a man taking part in the trial, perception of the risk is less obvious. It is therefore worth explaining that the medicinal product could have toxic effects on sperm quality and thereby present a risk to the development of the foetus in case of pregnancy.
- The information concerning these risks must clearly establish, for both female and male participants, that any pregnancy must be avoided by the female participant or the partner of a male participant.
- If there is no risk and male participants do not need to take any contraceptive measure to avoid their partner becoming pregnant, this should be specified.

  If the participant is required to take contraceptive measures on a precautionary basis but without the knowledge of a possible toxic effect on sperm quality, the participant must be informed.
- Consider the measures to be taken if (despite everything) a pregnancy occurs in a partner of a male participant.
    - If the partner of a male participant becomes pregnant, the participant should be encouraged to inform the investigator to allow the best option to be chosen for her and the foetus/baby. An option may involve this pregnancy being included in a monitoring programme.
    - The pregnant partner must be informed of the collection of personal health data (progress of the pregnancy, birth and first months of life of the child, where applicable).
    - A separate ICF, which must be reviewed by the Ethics Committee, will explain the reasons for monitoring the pregnancy and therefore the risks to the unborn child. It will also present the female participant's rights to (take part in) this monitoring programme (voluntary nature of participation, possibility of withdrawing consent, protection of privacy, responsibility for damages).
    - In situations where the sponsor has reasons to suspect a toxic effect, the information must be explicit.
    - It is also important, depending on the size of the risk, to insist that the participant informs his partner(s) that he is taking part in a clinical trial with a medicinal product that is potentially toxic to the foetus and the measures they must take together in terms of contraception.
    - The male participant must therefore also be informed that he must not under any circumstances donate sperm.
- Consider the measures to be taken if (despite everything) a pregnancy occurs in a participant:
    - Add the follow up measures described in the protocol.

[If applicable] This section is intended solely for participants with a potential to get pregnant or participants who may get their partners pregnant.

Female participant**:** Because the effects of [name of IMP and/or comparator] on an unborn child or infant are not known, you will not be allowed to take part in this trial if

- you are pregnant,
- wish to become pregnant in the near future or
- if you are breastfeeding.

It is also not allowed to do egg/ovum donation during and after your participation in the trial for up to [number] days/months after the last [name of IMP/comparator] intake.

If you take part in the trial, you must use one of the [choose: following [or] authorised] methods of contraception, during the trial [if applicable] and up to [number] days/months after the last dose of the trial: [if applicable: list the authorised methods]. Please discuss this point with your investigator if this applies to you. Please inform the investigator in case you would decide during the trial to change your method of contraception.

You will be required to have a pregnancy test [(blood/urine) at trial start before the first dose of [name of IMP/comparator]. [choose:] A repeated pregnancy test must be done if you miss any periods or your menstrual cycle becomes irregular. [or] It may be required to continue testing during and even after the dosing phase of the trial.

Nevertheless, if you become pregnant during the trial, you should inform immediately the investigator and your treating physician. (S)he will ask you to sign a specific informed consent (for the pregnant participant) to follow up your pregnancy and its outcome.

Male participant:

[Example in case of risk] Taking [name of IMP/comparator] could have an effect on your sperm and could lead to an unknown risk for an unborn child.

If you take part in the trial, you must use contraception and you should not be sperm donor for the duration of the trial and up to [number] months or [number] days after the last dose of the [name of IMP]. Please discuss this point with the investigator if this applies to you.

You commit to inform your female partner of your participation in this trial and of the potential risk to an unborn child.

Nevertheless, if your partner becomes pregnant during the trial, you should inform immediately the investigator. If you agree, (s)he will contact your partner to ask her to be followed up during her pregnancy and its outcome and to sign a specific informed consent (for the pregnant partner).

7. What If something goes wrong within the trial?

Even if there is no fault, the sponsor is liable for harm caused to you whether directly or indirectly related to your participation in the trial. The sponsor has taken an appropriate insurance (a so called “NO FAULT INSURANCE”) for this liability (Ref. 2). A copy of the insurance certificate can be obtained from the investigator or trial staff.

If you (or in the event of death, your rightful claimants) seek compensation for a harm to your health as a direct or indirect result of participating in the trial, you must inform your investigator or trial staff promptly.

If the investigator believes that a link between the new or worsened health problem(s) and the trial is possible, he/she will inform the trial sponsor. The sponsor will then immediately initiate the declaration procedure to its insurance company. If the company considers it necessary, it will appoint an expert to assess whether there is a link between your reported health problem(s) and the trial. The insurance does not cover the natural progression of your disease/condition or the known side effects of the treatment you would have received without taking part to the trial (*that is* your standard treatment).

Whenever you feel it is appropriate or if you or your rightful claimants disagree either with the investigator or with the expert appointed by the insurance company, you may contact the insurance company or proceedings may be brought against the insurance company. You will find the contact details on the front page of this form.

8. What if other treatment options or new information on the IMP become available during the course of the trial?

During the course of the trial, important new information might become available, possibly affecting your decision to (further) participate. For example other treatments for your disease/condition or important new information on the IMP may become available. It is the duty of the investigator to discuss this new information with you and to give you the opportunity to re-consider your participation in the trial.

If you decide to stop taking part in the trial or if you are no longer able to participate, your investigator will see to it that you continue to receive the best possible medical care.

9. Can my participation in the trial end prematurely?

As explained in detail below, your trial participation may end prematurely when

- you decide to withdraw your consent,
- the investigator decides to end your trial participation, or
- other entities interrupt or end the trial.

In any case, if your trial participation ends prematurely, the investigator will discuss your future medical care with you. The sponsor can continue to retain and use any data that have already been collected before the end of your participation. This is to avoid skewing / biasing results of the trial (as described in I. § 12.4., page 22).

If you experience a side effect at the moment of stopping the IMP, the investigator may contact you in the future to see if it has resolved or not after the end of the trial participation.

If you experience a new side effect after the end of your trial participation you may contact the investigator to ask for a follow-up.

9.1. You decide to withdraw your consent

You are entitled to withdraw your consent for any reason, at any time, without having to justify your decision. However, for your safety, you should inform the investigator of your decision. Although it is not mandatory, it may be useful for the investigator and for the sponsor to know the reason of your decision (for example side effects, frequency of clinical visits,…).

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

- the treatment with the IMP, and
- all trial-related visits and examinations.

Please discuss with your investigator to evaluate the practical modalities of your withdrawal (in light of your situation), including any follow up-visits or procedures.

In any case, no new data will be sent to the sponsor.

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

The biological samples that have been collected (but not tested) before the withdrawal of your consent and the data obtained from it, can also still be used by the sponsor. You may ask for a destruction of those samples. If this impacts the validity of the trial, the destruction may be postponed till the end of the trial.

In case you have signed an additional consent form for the use of your samples in future research, and you choose not to withdraw this separate consent, your samples can still be used for this research.

9.2. The investigator decides to end your trial participation

The investigator may end your trial participation because

- you become pregnant during the trial,
- it is better for your health,
- he/she determines that you are not following the instructions given to participants, or
- any other reason that will be explained.

9.3. Other entities may interrupt or end the trial

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

- the information gathered shows that the IMP is not effective (does not deliver a sufficient level of improvement in the health of the trial participants),
- the IMP causes more (serious) side effects than anticipated, or
- any other reason that will be duly motivated by such party.

10. Which treatment will I get after my participation in the trial?

After you stopped the treatment with the IMP, the investigator will assess your health. If necessary, he/she will prescribe you the best standard treatment available or refer you to another treating physician of your choice.

[Choose one of the texts below]

The sponsor will give you post-trial access to the IMP after this trial [cfr Declaration of Helsinki, art. 34] if

- the benefit/risk ratio is favourable for the participants and no satisfactory treatment is available on the market in Belgium,
- the competent Belgian health authorities approve this access and
- the development and manufacturing of the IMP is continued.

[or]

If you have taken part in the entire trial, the investigator may invite you to take part in an extension trial that will allow you to receive [name of IMP] for a certain period of time. The investigator will invite you to participate if he/she considers that this option is appropriate for you and you meet the inclusion criteria for the extension trial. Taking part in this extension trial is voluntary.

11. Will my participation in the trial involve extra costs for me?

11.1. Examinations and treatments paid by the sponsor

[The sponsor should be aware that in Belgium trial patients are not excluded from social security. It is prohibited to charge the participant/social security with trial related examinations.]

The sponsor has arranged to compensate the hospital or site for

- the time devoted to the trial by the investigator and the trial staff,
- the visits/consultations and all scheduled examinations specific to the trial,
- the investigational treatment (IMP and any other medication and material specifically used for the trial).

[The patient should have a clear view on which treatments/examinations/visits are trial specific (and therefore paid by the sponsor), and which ones belong to the standard of care. The sponsor should indicate in the annex (referred to in this section) which visits, treatments and examinations are specific to the trial and are therefore charged to the sponsor. This can be done by using a superscript (e.g. TS) or by putting these items in bold).

If discussions between sponsor and site are not yet finished at the time of submission of the dossier, the sponsor provides, at the time of submission, the annex without TS-indications. After the approval of the dossier and after finalization of the contract with the site, the annex(es) including the TS-indications, is/are provided as a notification to the FAMHP (National Contact point, law 2017) or central EC (law 2004). The sponsor provides the site-specific annex to each investigator. The annex can only be used after it has been notified.
Since the annex will be site specific, it should contain the name of the site and two version numbers, i.e. the version number of the ICF to which it belongs, and a separate version number of the annex itself. Example of a footnote: Annex version 2.3 to the Informed consent form (version 2.0), dated dd/mm/yyyy.

The correctness and completeness of this annex as well as its adequate update, is a shared responsibility of the sponsor and the investigator. In addition, the investigator is responsible to keep this information up to date in the participant's medical file , and keep the sponsor informed.]

[Choose one of the below texts.]

In the annex to this ICF you will find the treatments or examinations that you will have to undergo, with the specifications which ones are trial specific and which ones are part of your standard care. The treatments and examinations that are trial specific will be paid by the sponsor and will not be charged to you. The standard procedures or examinations for your condition (i.e. standard of care) will be charged to you or your mutual insurance fund (Belgian social security).

If you need more details or if you are not affiliated with a mutual insurance fund (Belgian social security), please contact the trial staff.

[OR]

You will find in the text and/or tables and/or or flow charts below the procedures and examinations which are specific for the trial and therefore will not be charged to you as a participant. The other procedures and examinations that belong to the standard of care for your condition, will be charged to you or your mutual insurance fund (Belgian social security).

[add tables & flow charts]

The visits and treatments which are a consequence of a side effect are also considered as trial specific.

11.2. Other expenses paid by the sponsor

[The sponsor should also specify clearly which other expenses will be compensated and the amount of the compensation, e.g. Travel costs: a fixed amount per visit, the amount per km or the reimbursement of the exact costs, …. If necessary, the information can be listed in a table. If contraception is mandatory, the compensation should be specified as well.]

[Choose one of the below texts:]

You will receive a compensation for the following expenses based on the receipts: transportation costs (fuel, parking fees, public transport), meals, mandatory contraception (birth control), medication needed to treat side effects, sun cream, …

The trial staff shall contact you for the practical arrangements.

[OR]

You will receive a compensation for the following expenses [examples are given in the following table]:

Type	**Amount**
Mandatory contraception	Reimbursement of patient's cost
Travel costs	[number] EUR per visit
Fuel	[number] EUR per kilometer (traject domicile-site)
Parking	Reimbursement of fee
Public transport	Reimbursement of fee
Meals	[number] EUR per visit
Medication needed to treat side effects	Reimbursement of patient's cost
Sun cream	Reimbursement of patient's cost
Time investment and efforts	[number] EUR per visit / trial
Hotel costs	[number] EUR per stay
…	

The trial staff shall contact you for the practical arrangements.

12. Which data are collected about me during the trial and what will happen with them?

12.1. Which data are collected and processed during the trial?

The collected and processed personal data concern information about your health and medical condition. This includes your medical history, some of your background information (for example your age, sex, and ethnic origin) and the results of examinations required by the trial.

12.2. How will the investigator treat my personal data?

The investigator is bound by professional secrecy about the data collected.

This means that he/she will never reveal your identity, including in a scientific publication or a lecture and that he/she will encode your data (*that is* by replacing your identity by an identification code in the trial) before sending them to the sponsor.

Therefore, the investigator and the trial staff under the responsibility of the investigator, will be the only ones able to establish a link between your identity and the data transmitted during the trial, with the exceptions listed under section 12.6.

The data transmitted to the sponsor will not allow the sponsor to identify you.

12.3. What will happen to information about me collected during the trial?

Your participation in the trial means that your personal data

- are collected by the investigator, and
- are used in an encoded form by the trial sponsor.

The investigator and the sponsor can only use the encoded personal data for research purposes in connection with scientific publications within the context of the trial that you participate in, or for a broader use of the encoded data if described below.

In addition, the sponsor may provide access to the encoded data to external researchers (that are not involved in this trial). In the event an external researcher wants to use the data in a project not yet described in this document, this project will have to be approved by an Ethics Committee. If your encoded trial data are sold, you will not benefit from this.

12.4. How will my data be handled?

[Information on the legal base for data processing.]

Your trial data will be processed in accordance with the General Data Protection Regulation (GDPR, Ref. 3) and the Belgian law on data protection of 30th July 2018 (Ref. 4). The sponsor is responsible for this processing.

Processing your personal data in this trial is allowed because we are conducting scientific research and [choose from one of the following options]

- You have given your **consent.(a)**
- we have to comply with a **legal obligation, namely** [define legal obligation, e.g. transfer of data to other competent authorities]**,** to which we [name(s) of controller(s)] is/are subject. (b)
- we have to perform a task carried out in [choose:] the **public interest** [or] in the exercise of official authority vested in us, namely [define e.g. advancing of science]. (c)
- we [name controller who has a legitimate interest] have **legitimate interests** because [name what is your legitimate interest, e.g. quality improvement of a product. Remark: it should be a legitimate interest for the sponsor. In this case the sponsor cannot be a public body.] (d)

[For your information, the board of RUZB/CHAB decided the following (November 2018):

- University Hospital is controller for the healthcare data collected in the Electronic Patient Dossier (EPD).
- University Hospital is processor for the data that will be processed in the Electronic Case Report Form (eCRF) on demand of the sponsor.
- University Hospital is controller in case of academic research.]

12.5. Do I have access to my data collected and processed during the trial and can I rectify them ?

You are entitled to ask the investigator what data are being collected about you and how those data will be used in connection with the trial.

You have the right [choose from the following options]

[The letters after the options refer to the legal base described above. If f. i. the legal base “consent (a)” is chosen, the sponsor may remove the options followed by an (a), thus limiting the rights. Be aware that limiting these rights is a possibility, but it has to be motivated in this document that these rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

Appropriate safeguards must be in place and shall ensure technical and organisational measures, in particular in order to ensure respect for the principle of data minimisation. Those measures may include encoding provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.

It is highly recommended to contact your data protection officer to inquire about the necessary and appropriate safeguards.]

- to inspect and access these data (a, b, c, d)
- to have all your data erased (a, b, c, d)

- to receive the personal data that are collected (This right is only granted by the legal basis “consent” and automated processing - however, no restriction is possible here.)
- to ask for correction if they are incorrect, (a, b, c, d)
- to restrict the processing of your data. (a, b, c, d)
- to object to the processing of your personal data (a, b, d)
- to withdraw your consent for the processing of personal data. (a), However personal data collected before withdrawal will be kept to avoid skewing of results in the trial. [if after withdrawal b, c or d can be used]

[If applicable] Your right [choose from the following options]

- to inspect and access these data (a, b, c, d)
- to have all your data erased (a, b, c, d)
- to ask for correction if they are incorrect (a, b, c, d),
- to restrict the processing of your data. (a, b, c, d)
- to object to the processing of your personal data (a, b, d)

is postponed for the following reasons, …[add why the rights are limited], including to avoid skewing of results in the trials (e.g. In case of blinded medication). Please ask your investigator when you can have access to your personal data.

[If applicable] It is not possible [choose from the following options which have been deleted in the first paragraph]

- to inspect and access these data (a, b, c, d)
- to have all your data erased (a, b, c, d)
- to receive the personal data that are collected (c)
- to ask for correction if they are incorrect, (a, b, c, d)
- to restrict the processing of your data. (a, b, c, d)
- to object to the processing of your personal data (a, b, d)

for the following reasons, …[add why the rights are limited], including to avoid skewing of results in the trial.

12.6. Who, other than the Investigator and his staff, has access to my personal data?

To verify the quality of the trial, it is possible that your personal **un**coded data or information in your medical records relevant for the trial, will be examined by people outside the trial staff but under the responsibility of the investigator. These persons must be subject to professional secrecy or a confidentiality agreement. The following might be considered:

- the personnel designated by the sponsor of the trial (MONITORS and AUDITORS), and people or organisations providing services for or collaborating with the sponsor. They will however never transfer your name and contact details to the sponsor.
- inspectors of competent health authorities worldwide
- an independent audit group
- people designated by the Ethics Committee

For the needs of the trial, the encoded trial data may be sent to other EU and non-EU countries and may be reviewed by

- personnel (other than the inspectors) of competent health authorities of Belgium (Federal agency for medicines and health products, FAMHP) and other EU and non-EU countries,
- the evaluating Belgian Ethics Committee(s),
- external researchers,
- the sponsor of the trial, personnel designated by the sponsor, and people or organisations providing services for or collaborating with the sponsor, and/or
- group companies of the sponsor in Belgium, and in other EU and non-EU countries.

The European regulation and the Belgian legislation on data protection have requirements for transferring data to non-EU countries. The sponsor must ensure equivalent guarantees regarding personal data protection standards before transferring the encoded data to non-EU countries. If for this purpose, there is a data protection agreement, a copy of this agreement may be obtained via the investigator. You can always contact your investigator to obtain more information about any such transfers.

12.7. [optional, only for autologous ATMP trials] Except the investigator and his staff, who else has access to my data in this autologous ATMP trial?

In this trial an autologous cell-therapy medicinal product (ATMP, advanced therapy medicinal product) is tested. The ATMP is made by transforming your own cells. It will be used as a medicinal product for your sole benefit. For this type of trials, specific rules exist about access to the data in the trial . The managing physician of the Production Establishment that makes the ATMP must have access to some relevant

data about you in **un**coded form. This is necessary to be able to guarantee the quality, safety and traceability of this medicinal product (Ref. 5).

12.8. What will happen to the results of the trial?

After trial closure, a description and the results of this clinical trial will be published in specialised medical journals. A copy of the scientific publication [if applicable:] or a summary for laypersons can be obtained from the investigator or the trial staff.

A description of the trial will also be available on https://www.clinicaltrialsregister.eu/ and/or https://www.Clinicaltrials.gov. You can search these websites at any time using the trial number given on the front page of the informed consent form. The websites will include a summary of the results within 1 year after the end of the trial (Ref. 6).

These websites or publications will not include information that can identify you.

12.9. Will my data be used for other purposes than for the trial in which I take part?

[Choose:]

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

[OR]

The results of the trial will be used to answer the scientific questions of the trial. In addition, the sponsor would like to use your data obtained from this trial, in connection with other research and development activities (and the associated scientific publications). These activities may concern

- the way [name of IMP] and drugs of the same group work,
- the disease/condition for which [name of IMP] is evaluated in this trial or
- other diseases and health problems which could benefit from [name of IMP], or from related diagnostic tests.

Any additional research outside of the trial, must be approved by a Belgian recognized Ethics Committee.

[Where the processing for a purpose other than that for which the personal data have been collected is not based on the participants' consent or on a Union or Member State law, the sponsor shall, in order to ascertain whether processing for another purpose is compatible with the purpose for which the personal data are initially collected take into account, inter alia:

(a) any link between the purposes for which the personal data have been collected and the purposes of the intended further processing;

(b) the context in which the personal data have been collected, in particular regarding the relationship between participant and the sponsor;

(c) the nature of the personal data, in particular whether special categories of personal data are processed, pursuant to Article 9 of the GDPR, or whether personal data related to criminal convictions and offences are processed, pursuant to Article 10 of the GDPR;

(d) the possible consequences of the intended further processing for data subjects;

(e) the existence of appropriate safeguards, which may include encryption or encoding.

It is highly recommended to contact your data protection officer to inquire about this compatibility and to decide if consent will be the chosen legal basis for the processing in these other research and development activities and if the sentence below should be included For more information consult the GDPR articles 5, 6 and 89.]

At the end of this form you agree or disagree to the use of your trial data for other purposes by ticking the appropriate check-box in Chapter II, page 31.

12.10. How long will my data be kept?

After the end of the trial your encoded data will be retained for at least 25 years (Ref. 7) to ensure the validity of the research. This will also be the case if you stopped trial participation prematurely.

13. Which biological samples are collected from me during the trial and what will happen with them?

13.1. Which biological samples are collected from me during the trial?

Biological samples are samples of human body material (for example blood, tissue, urine, faecal stool, ….)

In this trial, the following biological sample(s) will be taken: [specify in brief]

[According to the law on human body material, each person that is processing human body material should ensure the traceability of this material. More information can be found in the law on human body material of 19/12/2008 (Ref 5). Therefore the following paragraph (§ 13.2) should be included.]

13.2. What will happen to the collected biological samples?

The collected biological samples will be managed and stored at [add name and location of the department or company (central lab) managing the biological material for the sponsor] for [number] years.

These biological samples will be analysed for the objectives of the trial.

[In case of genetic analyses, include the following sentences:]

Genetic analyses will also be performed on your samples. The purpose of these analyses is … [explain the purpose].

[Choose:] These genetic analyses are optional and not a prerequisite for your participation to the trial. You agree or disagree to take part in these genetic analyses by ticking the appropriate check-box in Chapter II, page 31.

[OR]

These genetic analyses will deliver essential information for the trial. If you do not want these analyses to be conducted, you will not be allowed to participate in the trial.

[According to the law on human body material of 19/12/2008, (Ref 5)., if upon analysis of human body material data are obtained which are significant for the persons health status, the person shall be informed of this information. It is an ethical obligation to also inform the blood relatives of these findings, therefore include one of the following sentences.

[Choose:]

[In case biological samples are **not** anonymized:]

It may happen by chance and in addition to the trial objectives, that the results of the analysis of your biological samples reveal information that may be important to your health or the health of your blood relatives. These data are called ”incidental findings” and will be treated as described in Chapter I, § 15, page 30.

[OR]

[In case biological samples are anonymized:]

It may happen by chance and in addition to the trial objectives, that the results of the analysis of your biological samples reveal information that may be important to your health or the health of your blood relatives. These data are called ”incidental findings”. In this trial some biological samples will be anonymized. Anonymization means that the your biological samples and your personal data cannot be linked to your identity any longer. Therefore, these incidental findings cannot always be treated as described in Chapter I, § 15, page 30, and you cannot be informed of the results of their analysis.

If you do not agree with this anonymization [choose:] your samples will not be included in the optional genetic analysis part of the trial [or] you cannot participate in this trial.

13.3. How will my biological samples be handled?

The procedure to encode your biological samples is the same as that used for your personal data (see I § 12.3, page 22, Ref. 8). Samples sent to the sponsor or to organisations working in collaboration with the sponsor, will only be labelled with your trial identification code.

As part of the trial, the sponsor might transfer (a part of) your samples to a laboratory that is working with them. This laboratory may only use your samples as specified in this document. The tracking of your samples will be ensured by the sponsor unless you have accepted anonymization of your samples.

Your biological samples are deemed to be 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 have commercial value.

13.4. What happens with any remainders of biological samples once the analyses described in this document have been carried out?

The sponsor shall use the biological samples within the context of the trial as described above.

[If remainders of samples will be destroyed mention here as text:] Your biological samples will be destroyed once the analyses for this trial have been carried out.

You may also ask for a return of the remainders of your biological samples, if they could still be usable for your benefit. Please contact your investigator or the trial staff for this.

[In case of a secondary use of samples, *i.e.* in case of additional research which is not clearly described in the protocol, add the following sentences:]

Since scientific progress in this area is constant, the sponsor would like to, with your consent retain the remainders of your biological samples for [number] years. The sponsor will use them for future research, outside the trial that you will participate in, to better understand the disease, its treatment and the responses to this treatment, and [name of IMP(s)/comparator]. The retention of the remainders of your samples goes together with the retention of the accompanying encoded personal data.

You agree or disagree to the retention of the remainders of your biological samples for future research by ticking the appropriate check-box in Chapter II, page 31.

If you agree, any future research, additional to what is described above, may only be conducted according to the legislation on the use of human tissue material (Ref. 9) and with the approval of a Belgian recognized Ethics Committee. As a general rule, you will be asked to sign an additional informed consent form in which the additional research is specified.

[The proposed text above covers most cases. In case of a secondary use of the remainders of the samples that is already clearly described in the protocol, the text as well as the consent in chapter II have to be adequately adapted. Please check the "Compendium Biobank" for more information (https://www.famhp.be/en/news/human_body_material_european_tissue_establishment_compendium).]

13.5. Will any additional biological samples be collected and used for additional research?

[If no additional biological samples are collected and the remainders of the biological samples will be destroyed, put here as text:] In this trial, no additional biological samples will be collected. [or] Not applicable

[Only in case the research is already clearly described in the protocol] With your consent, the sponsor would also like to invite you to take part in additional research intended to gain a better understanding of the disease and its treatment or [name of IMP and comparator]. Your participation in this additional research is optional and will involve donating additional biological samples. The additional biological samples will be retained for [number] years. It concerns the following samples: [mention the biological samples that will be collected additionally].

[Choose:] More information on this additional research is described in Chapter [number], section [number]. You agree or disagree to donate additional biological samples and participate in the described research by ticking the appropriate check-box in Chapter II, page 31.

[OR]

We will provide you with information specific to this research in a separate informed consent form. If you want to participate in this additional research we ask you to sign this separate informed consent form.

14. Who has reviewed and approved the trial documents?

The documents of the trial have been reviewed by

- The Belgian competent health authorities (FAMHP) or if applicable by the competent national health authorities of other EU members states and
- An independent Belgian Ethics Committee

It is the task of the competent health authorities and the Ethics Committees to protect people who take part in a trial. The health authorities will ensure that the trial is conducted in accordance with the applicable legislation.

You should not under any circumstances take their approval as an incentive to take part in the trial.

15. What happens in case of incidental findings?

If by chance and in addition to the trial objectives a result is discovered during the trial that may be important to your health or the health of your blood relatives (called ”incidental findings”), the sponsor will inform the investigator. With your consent the investigator will notify you and your treating physician about your results and potential consequences. If necessary, the investigator and/or the treating physician will advise you on the next steps.

You agree or disagree to being informed of it by ticking the appropriate check-box in Chapter II, page 31.

CHAPTER II - INFORMED CONSENT

[General remark to the sponsor: This section may only contain information that is mentioned in the previous sections of this document.]

PARTICIPANT

[Limit this section to maximum 3 pages.]

PREREQUISITES FOR YOUR PARTICIPATION IN THE TRIAL

- I declare that I have been informed of and that I understand the purpose of the clinical trial, its duration, possible risks and discomforts, the precautions that I have to take and what is expected of me. My rights have been explained to me and I have understood those rights.
- I have had enough time to think about taking part in this trial and to discuss it with a trusted person (for example friends, relatives, treating physician, …).
- I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.
- I understand that my participation in this trial is voluntarily and free from any coercion and that I am free to stop at any time my trial participation.
- I understand that data about me will be collected and that they will be treated confidentially.
- [If “consent” is chosen as legal base, use:] I agree to my personal data being processed as described in Chapter I, § 12, page 22.
- I understand that the sponsor has taken out an insurance in case I should suffer any damage in connection with my participation in this trial.
- I understand that when participating in this trial, I will not have any costs except those related to the standard of care treatment of my disease [if applicable:] (as described in the annex).
- I agree to my treating physician(s) being informed of my participation in this trial.
- I agree not to take part in any other trial at the same time without first informing the investigator or the trial staff, who might not permit me to participate for a good reason.
- I understand that I need to cooperate and follow the investigator’s and trial staff’s instructions regarding the trial.
- I understand that participation to the trial might end for me without my consent if I need other treatment, do not follow the trial plan, have a trial-related injury, or for any other justified reason.
- [In case of mandatory genetic analyses] I understand that genetic analysis will be conducted on my biological samples.
- [If anonymization of some samples:] I am aware that the results of the analysis of any anonymized biologicals samples and the possible remainders of samples will not be available for me (Chapter I, § 13.2, page 27).

- I certify that all the information I have given about my medical history is correct. I understand that my failure to inform the investigator or designee about any exclusion criteria may harm myself.

[If applicable:] OPTIONAL CONSENTS WHICH ARE NO PREREQUISITE FOR YOUR PARTICIPATION IN THIS TRIAL.

1. [If applicable] As specified in Chapter I, § 12.9, page 26, the sponsor would like to be able to use your data obtained from this trial in connection with other research and development activities (and the associated scientific publications) on the condition that such research purposes have been approved by a Belgian recognized Ethics Committee.

   Do you agree with the use of your data obtained in this trial for other research purposes?

   (Tick as appropriate. If you leave this question open, we assume the answer is 'I do not agree'.)

☐ **I agree**	☐ **I do not agree**

2. [If there are optional genetic analyses foreseen in the current trial protocol]

   As specified in Chapter I, § 13.2, page 27, optionally, the sponsor will be conducting genetic analysis on your biological samples. [If applicable:] I am aware that the results of these genetic analysis will not be available for me due to the reason explained.

   Do you agree to the sponsor conducting genetic analysis on your biological samples?

   (Tick as appropriate. If you leave this question open, we assume the answer is 'I do not agree'.)

☐ **I agree**	☐ **I do not agree**

3. [If applicable] As specified in Chapter I, § 13.4, page 29, the sponsor would like to retain the remainders of your biological samples for [number] years for future research outside the trial that you will participate in. The samples will be used to better understand the disease, its treatment and the responses to this treatment, and [name of IMP(s)/comparator].

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

   (Tick as appropriate. If you leave this question open, we assume the answer is 'I do not agree'.)

☐ **I agree**	☐ **I do not agree**

4. [If additional research on biological samples is foreseen in the current trial protocol]

   As specified in Chapter I, § 13.5, page 30, the sponsor would like to invite you to take part in additional research intended to gain a better understanding of the disease and the IMP(s) being tested. Your participation in this additional research is optional and will involve donating additional biological samples.

   Do you agree donating additional biological material and participating in this additional research?

   (Tick as appropriate If you leave this question open, we assume the answer is 'I do not agree'.)

☐ **I agree**	☐ **I do not agree**

5. As described in Chapter I, § 13, page 27, and § 15, page 30, it may happen that incidental findings are discovered that may be important to your health or the health of your blood relatives.

   If this happens: do you want the investigator to inform you (directly or via your treating physician) of this result?

   (Tick as appropriate. If you leave this question open, we assume the answer is 'yes, I want to be informed'.)

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

6. [If anonymization of some samples:] Do you agree with the anonymization of your samples as described in Chapter I, § 13.2, page 27 ?

   (Tick as appropriate. if you leave this question open, we assume the answer is 'I do not agree'.)

☐ **I agree**	☐ **I do not agree**

I consent to take part in the trial, [if optional questions have to be answered by the participant:] with the above restrictions and I have received a signed and dated copy of all pages of this document.

Participant's surname and first name:

Date (DD/MMM/YYYY):

[if screening and randomization occur on the same day] Time:

Participant's signature:

[If the trial may include incapacitated persons.] ***LEGAL REPRESENTATIVE (REF. 10)***

I declare that I have been informed that I am being asked to take a decision on whether or not to take part in the clinical trial for the person I represent, considering his/her best interests and taking into consideration his/her likely wishes. My consent applies to all the items listed in the consent of the participant.

[In situations where the incapacity is temporary.]

I have also been informed that as soon as the clinical situation allows, the person I represent will be made aware of his/her participation in a clinical trial and from that point will be free to continue with this participation or end it by signing or refusing to sign this consent form.

I have received a signed and dated copy of this document.

Legal representative's surname and first name:

Relationship to the participant:

Date (DD/MMM/YYYY):

[if screening and randomization occur on the same day] Time:

Legal representative's signature:

[If a witness / interpreter is present.] ***IMPARTIAL WITNESS / INTERPRETER (REF. 11)***

I, the undersigned (Tick as appropriate),

☐ Impartial Witness

☐ Interpreter

was present during the entire process of informing the participant and I confirm that the information on the objectives and procedures of the trial was adequately provided, that the participant (or his/her legal representative) apparently understood the trial and that consent to participate in the trial was freely given.

I declare furthermore that acting as an impartial witness, I am independent of the sponsor and the investigator.

Impartial Witness / Interpreter surname and first name:

Impartial Witness / Interpreter qualification:

Date (DD/MMM/YYYY):

[if screening and randomization occur on the same day] Time:

Impartial Witness / Interpreter signature:

INVESTIGATOR

[The investigator is the medical doctor or dentist that has conducted or supervised the interview with the participant. This might not be the Principal Investigator of the site. If another member of the trial staff also participates in the interview with the participant, this person may additionally sign the ICF as delegate. Nevertheless, the investigator always signs last.]

I, the undersigned investigator, confirm that

- the participant has been verbally provided with the necessary information about the trial, has been explained the content and has been given an original signed document.
- I have verified that the participant has understood the trial.
- I have given the participant sufficient time to agree to take part and to ask any questions.
- no pressure was applied to persuade the participant to agree to take part in the trial.
- I operate in accordance with the ethical principles set out in the latest version of the "Helsinki Declaration", the "Good Clinical Practices" and the Belgian Law (Ref. 12).

[Optional signature by a delegate]

Investigator's delegate, surname and first name:

Investigator's delegate, qualification:

Date (DD/MMM/YYYY):

[if screening and randomization occur on the same day] Time:

Investigator's delegate signature:

[Mandatory signature by the investigator]

Investigator's, Surname and first name:

Date (DD/MMM/YYYY):

[if screening and randomization occur on the same day] Time:

Investigator's signature:

GLOSSARY

[Add in this chapter an explanation of terms perhaps difficult to understand for the participant. Any abbreviations should be written in full in the text when used for the first time.]

DPA: The Data Protection Authority ensures that personal data are handled with care and thoroughly protected, and that your future privacy also remains guaranteed.

FAMHP: Federal agency for medicines and health products

IMP: investigational medical product

NO FAULT INSURANCE:

The sponsor is liable for any injury or any damage that the participant has suffered, and which is directly or indirectly related to the clinical trial. You do not have to prove any mistake in this respect.

MONITOR and AUDITOR

Both the monitor and auditor work for the sponsor.
The monitor takes care of a continuous quality check during the course of a trial. The auditor performs a quality check after the trial. They verify if the trial is being/was conducted according to the protocol, if the reported data are liable and if the clinical trial was conducted according the applicable rules.

REFERENCES

[1] The definition of interventional trial can be found in the Questions and Answers (draft) document of the European Commission which can be found in Eudralex Volume 10, Chapter V which is accessible via the following link: https://ec.europa.eu/health/documents/eudralex/vol-10_en#fragment1.

[2] [For studies not submitted in CTIS:] This is in accordance with Article 29 of the Belgian Law of 7 May 2004 related to experiments on humans. [For studies submitted in CTIS:] This is in accordance with Article 12 of the Belgian Law of 7 May 2017 on clinical trials with medicinal products for human use.

[3] 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.

[4] The Belgian Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

[5] Belgian Law of 19 December 2008 on the acquisition and use of human body material with a view to medical application to humans or scientific research, and the applicable royal decrees.

[6] In accordance with section 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/C 302/03). [From the moment the Clinical trial regulation enters into force : In accordance with article 37 of the Clinical trial regulation 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; sponsor have to provide summary results of clinical trials in a format understandable to laypersons.]

[7] In accordance with article 58 of the Clinical trial regulation 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.

[8] Belgian Law of 19 December 2008 on the acquisition and use of human body material with a view to medical application to humans or scientific research, and the applicable royal decrees.

[9] This is in accordance with Article 21 of the Belgian Law of 19 December 2008 on the acquisition and use of human body material with a view to medical application to humans or scientific research, and the applicable royal decrees.

[10] When a person of full age is incapable of expressing his will, legal representation must be used which is determined in successive order (administrator, or failing that, the spouse, the legal cohabiting partner, de facto cohabiting partner, an adult child, a parent, an adult brother or sister). [For studies not submitted in CTIS:] The regulation is laid down in article 8 of the law of 7 May 2004 on experiments on the human person. [For studies submitted in CTIS:] The regulation is laid down in article 11 of the law of Belgian Law of 7 May 2017 on clinical trials with medicinal products for human use.

[11] Use of an impartial witness is necessary when either the subject or the subject's legally authorized representative speaks and/or fully understands the language of the approved informed consent form, but cannot read and write due to any physical impairment or is visually impaired. An interpreter is necessary when the investigator doesn't speak the language of the patient.

[12] [For studies not submitted in CTIS:] Belgian Law of 7 May 2004 related to experiments on humans, and the applicable royal decrees. [For studies submitted in CTIS:] Belgian Law of 7 May 2017 on clinical trials with medicinal products for human use, and the applicable royal decrees.