**Model ICF for** **clinical investigations with a medical device on adult patients**

## Version history

|  |  |  |  |
| --- | --- | --- | --- |
| ***Version number*** | ***Supersedes version*** | ***Date of approval*** | ***Summary of changes*** |
| *1.1* | *1.0* | *16/05/2025* | *Correction of typos and translation errors* |
| *1.2* | *1.1* | *17/07/2025* | *Section 10:** *Addition of extra instructions*
* *Adaptation of the conditions for post-trial access to medical device*

*Section 12.1:** *Removing of the word “race”*
* *Addition of extra instructions*

*Section 12.3:** *Correction in the first bullet point of the last paragraph*

*Section 4:** *Addition of “scham procedure”*
 |

# 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 a (Ref. [[1]](#endnote-2)) clinical investigation with a medical device, that is assessed by an independent Belgian Ethics Committee recognized under the Belgian legislation of 7 May 2017. In other words, this ICF is intended for clinical investigations who are being evaluated following one of the next regulatory pathways:

* A clinical investigation with a CE-marked medical device used within the area of intended use, in the context of a Post-Market-Clinical-Follow-up, involving burdensome or invasive procedures.
* A clinical investigation with a CE-marked medical device used outside the area of intended use.
* A clinical investigation with a medical device for which CE marking has yet to be obtained.
* A clinical investigation with a medical device where CE marking is not provided, and the data is used for a conformity procedure.

The term “clinical investigation” will further on in this document be referred to as “trial”.

This template is available in three languages: English, French and Dutch. The sponsor should submit the ICF to the ethics committee in the official country languages of the regions where participants are recruited.

In most trials, patients are recruited. For this reason, the ICF template was adapted to this population. If the trial is designed to recruit only healthy volunteers, the sponsor should adapt the template to its specific situation. This means, among other things, that terms such as: patient, disease/condition/injury/impairment, alternative treatments, standard treatment, ... should be adapted to the situation of the healthy volunteer.

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](https://consultativebodies.health.belgium.be/en/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.)

The template contains headings that are used to format the table of contents. If headings are added to the document, copy the style of the already existing headings. More tips on formatting an automatic table of contents can be found [here](https://support.microsoft.com/en-us/office/format-or-customize-a-table-of-contents-9d85eb9c-0b55-4795-8abb-a49885b3a58d?ui=en-us&rs=en-us&ad=us).

## 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 advice:

* 1. Use the correct sentence structure (pay attention to problems of literal translation from English to French/Dutch, inappropriate choice of terms, etc.).
	2. Use short sentences (less than 12 words) and short paragraphs (less than 7 lines). Use bullet points where possible.
	3. Avoid technical jargon.
	4. For the same concept use the same terminology throughout the whole document. Examples: In this template the following terms are used:
		+ “Clinical investigation” 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.
	5. 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.
	6. 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.
	7. Use an attractive design with sufficient subtitles and white rules.
	8. If possible, involve a patient or patient association in the development of the ICF (in relation to comprehensibility, relevance of information).
	9. All pages of the document should be identified by the same version number of the ICF and the same date of issue.
	10. The pagination of the whole document will be presented in the format “page X/Y”. Where Y indicates the total number of pages.

No specific writing guidelines are currently available to inform patients about trials involving a medical device. However, the following guidelines, formatted for trials with a drug, can be used as a start to write a text in lay terms.

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 English ICFs, please refer to the writing recommendations for ‘Summaries of Trial Results for Laypersons’, available at 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 ICFs in a language other than English.

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.)

For the contact details, all data are site specific, except for data from the sponsor’s insurance company, the CT-College, the Federal Agency for Medicines and Health Products (FAMHP) and the data from the Belgian Data Protection Authority (GBA). Site specific contact details should be completed after the ICF has been approved by the Ethics Committee.

The phone number mentioned for the “Contact for urgent study-related questions” should be a hospital number (e.g., general number) where the participant can contact the doctor on duty 24h/7 days, with urgent questions about his/her health related to this clinical study. If necessary, the doctor on duty will contact the trial staff. 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:

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

This may be a person who watches over the protection of personal data within the study centre; for example, this could be the principal investigator.

* The “patient rights ombudsperson” can be replaced by the FAMHP or the CT-College, depending on the type of trial:

|  |  |
| --- | --- |
| Trials submitted through a procedure involving the CT College, e.g. submission under MDR, regulatory pathway: CE – outside the area of intended use. The "Patient Rights Ombudsperson" may be replaced by the "CT College". | e-mail:ct.college@health.fgov.be |
| Trials submitted through a procedure not involving the CT College, e.g. submission under- MDR, regulatory pathway: CE - within area of intended use - other trialsThe “Patient Rights Ombudsperson” may be replaced by the ‘Federal Agency for Medicines and Health Products (FAMHP)’. | e-mail:inspection@fagg.be |

*The ICF template version 1.0 for clinical investigations with a study drug in adult patients 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) was asked for advice on the GDPR aspects in this template on 28/06/2019. Based on the DPA's advice as received on 17/07/2019, each sponsor should apply the principle of accountability and adapt the template to its specific situation.*

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

*Version 1.1 of the ICF Template for clinical investigations with study drug in adult patients contains decisions taken by the Board of the College and some minor adaptations. The changes from version 1.0 are indicated in yellow.*

*This ICF template version 1.0 for clinical investigations with a medical device in adult patients is based on the ICF template version 1.1 for clinical investigations with study drug. Adaptations were made by BAREC's ICF Working Group to meet clinical investigation requirements for trials with a medical device. The adapted version was approved by the BAREC Board on 24/01/2025.clinical investigation.*

#

# Template

**INFORMED CONSENT FORM FOR CLINICAL INVESTIGATIONS WITH A MEDICAL DEVICE ON ADULT PATIENTS**

# [FRONT PAGES]

*Official lay title of the trial as given in the EUDAMED data base*

Official title of the trial: *Official title*

EU number: *Unique SIN (CIV) number and/or UDI number if already available*

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 (Ref.[[2]](#endnote-3)): *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 (*[*NL*](https://www.health.belgium.be/nl/gezondheid/organisatie-van-de-gezondheidszorg/delen-van-gezondheidsgegevens/gezondheidszorginstellingen)*)]*

Main address of site: *address of site*

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

[If changes are not included in an addendum to the ICF and an updated 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 and the participant. The sponsor has the choice of adding the table to the ICF here or as an appendix. An example is given below.]

## [If applicable:] Document Revision History

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

## Who can I contact in case of questions?

[The sponsor has the choice of including the table below at this place in the ICF or at the end of the document].

|  |  |  |  |
| --- | --- | --- | --- |
| **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°, E-mail |
|  | Contact for urgent study-related questions [not emergency department of hospital] | Urgent information, problems, concerns | Phone N° |
|  | Patient rights ombudsman from the site, [and if not possible contact the CT College]. | Concerns relating to your rights as a participant in a trial | Phone N° from the site [if not possible: ct-college@health.fgov.be] |
| Name and address of insurance company of the sponsor & contact person of the insurer | Insurance Company of the sponsor | In case of disagreement or complaint on a damage claim | Policy N°: numberAddress: address of the insurance companyPhone N°.: E-mail: e-mail address:  |
|  | 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 | +32(0)2274 48 00E-mail: contact@apd-gba.be  |

*● To manage complaints not resolved by the investigator, you can contact the study center ombudsman at the above address.*

*● According to the GDPR, you have the right to access the processing of your data. For questions about this, you can contact the Study Centre's Data Protection Officer at the above address.*

*● You also have the right to lodge a complaint about the way your data are processed with the Belgian supervisory authority responsible for compliance with data protection legislation: Data Protection Authority (DPA), above.*

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| --- |
| The trial at a glanceTo indicate that this chapter is different in style from the rest of the document, it is recommended to print it on coloured paper or include the content in a box with a coloured background.Please include in this chapter a brief (maximum 2-3 pages) summary of the most important aspects of the study. Please use very simple terms in this chapter so that everyone can understand this text.An example of this chapter is available via the following link: <https://overlegorganen.gezondheid.belgie.be/nl/ct-college> . The sponsor can check the readability of this chapter via the following online tools for French and English: <https://translatedlabs.com/lisibilit%C3%A9-du-texte> and for Dutch and English. <https://www.lt3.ugent.be/readability-demo/> . Note: This part of the ICF is mandatory and an agreement at Belgian level, within the Belgian Association of Research Ethics Committees (BAREC), consists of granting a refusal if this part is not present or inadequate based on the guidelines below. In case of any discussion, disagreement or contradiction regarding the contents of this document, only Chapters 1 and 2 are legally binding on the participant.The following questions can be used as guidelines: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 medical device be used?
5. Which most significant/painful examinations will be conducted?
6. What is the duration of the trial (for the participant and in general)?
7. Will the medical device produce side effects?
8. Is there an insurance cover in case something goes wrong within the trial?
9. May the participant get pregnant during the trial or conceive a child?
10. Who pays trial specific costs and what does the participant have to pay or not?
11. Will the data be treated confidentially?
12. Is the participant free to take part?
13. Who has reviewed and approved the trial documents?
14. Will the participant be able to continue treatment with the medical device after his/her participation in the trial?
15. Which commitments are expected from the participant? Please incorporate the following commitments:
	* to agree that the investigator informs the treating physicians regarding participation in the trial
	* not simultaneously participate in another interventional trial with drug or trial with medical device without informing the investigator or trial staff
	* to communicate the relevant information related to the state of health, other medication taken or the symptoms experienced
	* to always carry the “emergency card”
16. Who can give more information to the participant?
 |

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

## Why is this study being conducted?

[Please specify in this section the name of the medical devices, i.e. the experimental medical device(s), and the reference device(s). It is also recommended to include an image of the device or screenshots of the software (e.g. app)].

This clinical investigation (further referred to as ‘’trial‘’) will evaluate the medical device under investigation for the following medical purpose [insert manufacturer's intended purpose or new/additional purpose being investigated].

The purpose of this trial is to learn about: [add the objectives of the trial; specifying the mode of action of the medical device(s), the number of patients that have already received this device for this and/or for any other indication,…]

## Why am I being asked to take part?

[If applicable] You have been diagnosed with [name of disease/condition/injury/impairment].

You are being asked to take part in this trial because

[If the participant needs the inclusion/exclusion criteria to take a considered decision, please add a brief description of the main inclusion/exclusion criteria as set out in the protocol and which the participant can understand.]

[Choose:]

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

[or]

[If no alternative treatment is available:] For your disease/condition/injury/impairment, 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/injury/impairment] 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/injury/impairment, 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.

## 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 applicable] If other treatments are available for your [disease/condition/injury/impairment], the investigator or his/her delegate will discuss these treatments with you.

## 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/sham procedure/screening, comparing the medical device(s) with the placebo/sham procedure and/ or the reference device. If applicable, add information on the probability of the random assignment of the treatment.
* the method and frequency of usage, number of visits.
* the course of the trial: screening phase (including duration), trial phase (when to be started, start of usage of the medical device, the reference device, placebo/sham procedure 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.

Depending on the study, 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 which visits, treatments and examinations are certainly specific to the trial and are therefore charged to the sponsor. This can be done by putting these items in bold. The investigator is responsible for clearly informing the patient about what constitutes standard care and what is specific to the study.

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 following text and/or tables and/or flow charts 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 reimbursed by 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.

[add text, tables & flow charts]

Overall, your participation in the trial will last [choose] about [number] weeks/months and involve [number] visits [or] according to your health status. The study is expected to last a total of [number of] weeks/months.

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. Consultations and treatments resulting from an adverse reaction are also considered trial specific.

[In case of home use of the medical device by the participant:] We expect that you will use [name of medical device/ reference device] as described above.

## Will I benefit from the trial?

The information obtained during a trial may contribute to a better understanding of the use of the medical device under investigation or to the development of a new medical device for the treatment of yourself or future patients.

[If applicable] The medical device may or may not be beneficial for the treatment or the follow-up of your [disease/condition/injury/impairment] or relieving your symptoms. Even if it is beneficial to you, a potential return or worsening of symptoms, illness or disease is still possible.

## What are the possible risks and discomforts of taking part?

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

[Choose between the following statements:]

Participation in a trial involves some risk. It is possible that the use of the medical device [name of the medical device(s)/reference device(s)] may lead to side effects or discomforts. Some of these are already known, and some are not known. Even if previous studies have shown that the use of [name of the medical device(s)/reference device(s)] was normally well tolerated, you may still experience the following side effects:

[Per medical device/reference device: Add a list of the side effects and describe them briefly. Put irreversible side effects (if any) in bold.]

[OR]

It is possible that the use of the medical device may lead to some side effects or discomforts. However, based on the mechanism of action of the medical device, you are not expected to experience more side effects or discomfort compared to the standard treatment that patients receive for this [disease/condition/injury/impairment]. If you would not participate in this study, you could also potentially experience the following side effects:

[Per medical device/reference device: Add a list of the side effects and describe them briefly. Put irreversible side effects (if any) in bold.]

[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 medical device.]

[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 medical device 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 you think it has to do with the trial (or to [name of the medical device/reference device]), and even when it is already described in this document. If you need to use other medication or another medical device, discuss this with the investigator beforehand.** **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 use of the medical device/reference device.
* what happens if the participant does not benefit from the medical device/reference device.]
	1. 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 trial staff who take the blood will do all they can to minimize these discomforts.

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

[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/> and the link there called “Consensus text on radiation burden for inclusion in ICF concerning diagnostic clinical investigations using radiopharmaceuticals in healthy volunteers and patients”.

* 1. 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 medical device/reference device.]

Do not hesitate to ask your investigator for more explanation about the possible use of medicines, food supplements (including aromatherapy, phytotherapy, homeopathy..) and other medical devices during the trial.

* 1. 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 lifestyle restrictions (e.g. it is not allowed to travel, exercise, use alcohol or tobacco, certain foods, drinks, …). This is important for chronic patients.]

* 1. [optional] Can I get pregnant, conceive a child, or can I breastfeed during the trial?
* For a woman taking part in the trial, the exposition of the developing foetus to the medical device 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 medical device 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 trial with a medical device that is potentially toxic to the foetus and the measures they must take together in terms of contraception.
	+ [If applicable] 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 partner(s) pregnant.

Female participant**:** Because the effects of [name of medical device and/or reference device] 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 use of [name of medical device/reference device].

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 subject 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. [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 end of the trial.

Nevertheless, if you become pregnant during the trial, you should inform immediately the investigator and your treating physician. For safety reasons, the investigator wants to monitor your pregnancy and its outcome and may be required to share this data with the sponsor to comply with regulations on monitoring and reporting safety information regarding the product.

Male participant:

[Example in case of risk] The use of [name of the medical device/reference device] could affect 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 use of the [name of the medical device/reference device]. Please discuss this subject 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).

## 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 in accordance with the current European and Belgian legislation on clinical investigations. 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. [If applicable] The insurance does not cover the natural progression of your [disease/condition/injury/impairment] 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.

## What if other treatment options or new information on the medical device or the clinical trial 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/injury/impairment] or important new information on the medical device 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.

## 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 or to stop using the medical device
* the investigator decides to end your trial participation, or to discontinue your treatment with the medical device, 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. Data collected before you terminate your participation may continue to be used and retained by the sponsor as described in this form. This is to avoid skewing / biasing results of the trial (as described in I. § 12.4).

If you experience a side effect at the time you stop using the medical device, the investigator may contact you afterward to determine whether or not the side effect disappeared after your participation in the study ends.

If you experience a new side effect after stopping your participation in the trial, you may contact the investigator and ask for follow up.

* 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. Your choice will not affect your relationship with the trial staff, and you will also be able to participate in subsequent, new trials or studies without any difficulty.

However, for your safety, you should inform the investigator of your decision. Depending on your situation, the investigator will discuss with you the practical arrangements for withdrawing your consent, including any necessary follow-up visits or procedures. This will ensure that your participation can be safely terminated. 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 use of the medical device if not necessary as part of your standard treatment
* all trial-related visits and examinations.

No new data will be collected and sent to the sponsor.

[If applicable] 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.

[If applicable] 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.

[If applicable] In case you have given an additional consent 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.

* 1. [If applicable, e.g. not always applicable for implantable medical devices] You decide to stop using the medical device.

You may decide to stop using the medical device but agree to continue participating in the study and be contacted by trial staff.

If you decide to stop using the medical device, you may continue to come to the study-related consultations. The trial staff will ask you if they can contact you by phone, email or post to ask about your general health status. This will take place approximately every [number of] months for the rest of the study (end date [state the estimated end date of the study]). They may also ask your permission to look for this information in your medical records (or [if allowed by local regulations] in public records) until the end of the study. This information is important for the scientific value of the study and to correctly interpret its results. You are free to refuse such a regular contact. Your decision will not affect your future medical care.

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

* 1. The investigator decides to end your trial participation or to discontinue your treatment with the medical device

The investigator may end your trial participation because

* he/she thinks it is better for you (e.g. based on your test results, when you develop certain health problems, when the protocol defines that you should not get pregnant and you get pregnant anyway, ...),
* he/she determines that you are not following the instructions given to participants, or
* any other reason that will be explained,
* the entire study should be discontinued for all participants (see next paragraph).

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

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

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

[The availability of the medical device after study participation varies depending on the type (implantable - or non-implantable) of medical device.

For **non-implantable medical devices**, the following text should be used].

After you stopped using the medical device, 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. Selection of one of the texts below must be based on a reasoned assessment by the sponsor, in consultation with the investigator. This assessment has to take into account the nature of the medical device, the mode of action, the class and the purpose of the trial (i.e. exploratory, confirmatory,…). If continued use of the medical device after the study is not deemed to be justified, then it is also the responsibility of the sponsor to document this consideration transparently in accordance with applicable guidelines.]

The sponsor will give you free access to the medical device after this trial [cfr Declaration of Helsinki, art. 34] if

* the benefit/risk ratio is favourable for the participants and no other equivalent or satisfactory and reimbursable treatment is available on the market in Belgium,
* the competent Belgian health authorities approve this access and
* the development and manufacturing of the medical device is continued, and
* the nature and the mode of action of the medical device allow for it (this is for example not possible in case of short-term use of an experimental medical device)

[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 medical device] 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.

[For **implantable medical devices**, the following text should be included. Under no circumstances, should the implantable medical device be removed after study participation unless medically necessary (e.g. knee replacement, pacemaker, stent, cochlear implant, etc)].

After your participation in this trial, you will be able to continue using the implantable medical device. All future costs will be covered by [choose] the sponsor, since this medical device is still under investigation [or] you or your mutual insurance company (Belgian Social Security), since this medical device is already available on the Belgian market and is included as part of your standard care.

[If the implantable medical device proves to be unsafe] If the implantable medical device shows a defect after the end of the study, the device will be removed, and you will receive the appropriate standard care. The costs of associated procedures and investigations will be covered by the sponsor, and you will not be charged. [If applicable] The cost of the replacement medical device may potentially be charged to you or your health insurance company if, under standard care, you would receive a medical device available on the Belgian market. For more information, please contact your investigator or study staff.

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

* 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.]

As described in paragraph 4, the examinations and treatment specific to the trial will not be charged to you. The treatments and examinations that are part of the standard treatment for your situation will be charged to you or reimbursed by your health insurance company.

In other words, 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 (Medical device and any other medical device, medication and material specifically used for the trial).
	1. Other expenses paid by the sponsor

[The sponsor must inform the participant of the following:

* The different reasons for compensation and what amount of compensation is offered for each category. Use the table below for this purpose.
* The form of compensation (bank transfer, external supplier, etc.) should be defined, including alternative options.
* The timing and conditions of payments].

You will receive compensation for certain expenses related to your participation in the study. The reimbursement received by Belgian participants as part of this study are not subjected to income tax in Belgium.

The table below describes what you will be compensated for and the amounts you will receive. This compensation will be in the form of (bank transfer, external supplier, voucher, payment cards, etc.). The sponsor will pay your compensation quarterly. [If applicable] The sponsor will ask participants for receipts. These receipts are collected by the trial staff and sent to the sponsor in coded form. You have the right to withdraw your decision for any form of compensation for any reason at any time without having to justify your decision. If you encounter any problems in receiving your compensation, do not hesitate to contact the trial staff.

You will receive compensation for the following expenses [different examples of compensation are given in the following table. Delete redundant lines]:

|  |  |
| --- | --- |
| Type | Amount |
| Mandatory contraception, mandatory sunscreen, recommended egg, or sperm freezing, mandatory diet, etc. | Reimbursement of patient's actual costs, fixed amount |
| Travel costs, public transport, parking | [number] EUR per visit, [number] EUR per km, reimbursement |
| Meals and drinks | [number] EUR per visit |
| Hotel costs | [number] EUR per stay |
| Time investment and efforts |  [number] EUR per visit / procedure |
| … |  |

[Please add more information here whether personal data is needed for compensation. It should be mentioned whether this data is passed on to external vendors. The participant should always be offered equivalent choices regarding compensation. For example, if a participant does not want compensation for expenses via a payment card, he should be offered the option to be compensated via a method that does not involve passing on personal data to an external party, e.g., bank transfer/voucher via the study centre). This option must be clearly formulated in the paragraphs below. Likewise, the participant's consent should be asked via the relevant box in Section II].

[Example: The sponsor has appointed an external vendor who uses a [form of compensation via external vendor, e.g., payment card] to compensate you. If the vendor requires personal information from you, they must process your data in accordance with current European and Belgian data protection legislation. This [form of compensation] can be used in different shops. On this website you will find a list of all shops where you can use [compensation form]: [website].

You agree or disagree to this form of compensation by ticking the relevant box in Section II. If you do not agree, the sponsor will compensate the trial site. The trial site, in turn, will compensate you at the same rates as mentioned above through [form of compensation through the study centre, e.g., bank transfer/voucher].]

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

* 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 and sex) and the results of examinations required by the trial.

[If applicable, if data concerning ethnicity are collected and only when this is absolutely necessary for the trial] Ethnic origin data are collected to ensure that research data are processed in the broadest possible population.

[If applicable: If the study is designed to evaluate software that will process/analyse patient data, it should also explain how this software processes the data and whether this data will be destroyed at the end of the study].

[Investigators are allowed to collect only the personal data that are vital for responding to the research question, in accordance with the GDPR principle of data minimisation and proportionality. ]

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

The investigator (and the trial staff) is bound by professional secrecy or by a confidentiality agreement 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 (Ref. [[3]](#endnote-4)) (*that is* by replacing your identity by an identification code in the trial) before sending them to the sponsor. In other words, this code will not contain any personal identifier or combination of identifiers such as name, first name, initials, full or partial date of birth, file number, etc. [A detailed description of the identification code should be included in the protocol]

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 12.5.

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

[If applicable: If the study is set up by a sponsor that develops the software itself (= manufacturer), necessary measures/procedures should be taken to prevent the identity of the patient from being known to the sponsor/manufacturer].

* 1. How will my data be handled?

[Information on the legal base for data processing.]

Your trial data will be processed in accordance with the current European and Belgian data protection legislation.

[The sponsor is OBLIGATED to choose its own legal basis for processing encrypted data. This choice affects the sponsor and entails obligations. The choice must comply with Belgian and European legislation.

There are 4 legal grounds to choose from, indicated below by the letters a-d. Each legal ground gives participants certain rights and restrictions, which are described in section 12.4].

The reason your personal data may be processed for the purposes of the study is that it is processed for the conduct of scientific research and [choose from one of the following options]

* You have given your **consent. (a)**
* we must 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)

[It is possible for the sponsor to invoke multiple processing grounds within the study. However, only one legal ground may be chosen for each separate processing activity. Thus, the sponsor cannot invoke multiple legal grounds for the same processing, or switch between legal bases. What is possible is to choose legitimate interest for the collection of the personal data to carry out the study, but to invoke legal obligation as a processing ground for the safety reporting. For each processing activity, the sponsor must clearly indicate which processing ground it is invoking.

For your information,

* the sponsor is a controller for all processing activities carried out with the participants' personal data for the purposes of the study;
* the site/hospital conducting the trial is a processor for the processing activities carried out by the site/hospital with the participants' personal data for the purposes of the trial;
* the site/hospital conducting the trial remains a separate controller for the processing of the personal data in its patients' medical records for the provision of medical care to its patients and for its own academic research purposes].
	1. 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.

[Depending on the legal ground chosen in section 12.3, the following rights and restrictions will be selected.

If ‘Legitimate interest’ (d) was chosen as the legal ground, the text in this section SHOULD look like this:

“You have the right to access and review your personal data and to request a correction if it is found to be inaccurate. However, these rights will be postponed to avoid unblinding this study. It is impossible to have all your data erased, to object to its processing or to have that processing restricted. As this could cause biased study results."]

You have the right [choose from the following options]

[The letters after the options refer to the legal base described above. If 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 must 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 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, depending on the legal basis, from the following options, that were retained above as a right for the participant]

* 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 above as a right for the participant]

* 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)
	1. for the following reasons, … [add why the rights are limited], including to avoid skewing of results in the Who, other than the Investigator and his trial 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.

* 1. [optional, only for autologous ATMP trials] Except the investigator and his trial 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 in accordance with the Belgian legislation on the use of human bodily material.

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

After trial closure, a description and the results of this 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.ClinicalTrials.gov>https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en. You can search these websites at any time using the information on the front page of the informed consent form. [Choose] Within 1 year after the study's completion [OR] [on the date of publication accepted with a request for deferral], the website will contain a summary of the results in accordance with the European Commission's guidelines.

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

[If applicable, i.e., if the sponsor intends to use the study data for the FDA (Ref.[[4]](#endnote-5) ):] A description of this clinical study is available at <https://www.ClinicalTrials.gov>, as required by United States law. This website does not contain any information that could identify you as an individual. However, it may display a summary of the results. You can search this website at any time.

* 1. 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 only concern

* the way [name of medical device] and similar devices work,
* the [disease/condition/injury/impairment] for which [name of medical device] is evaluated in this trial or
* other diseases and health problems which could benefit from [name of medical device], or from related diagnostic tests.

Any additional research outside of the trial and therefore not described in the above points, 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, 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.]

[If applicable and if ‘consent’ is chosen as the legal ground for data processing] At the end of this form, you agree or disagree to the use of your trial data for other purposes by ticking the appropriate checkbox in Chapter II.

* 1. How long will my data be kept?

After the end of the trial your encoded data will be retained for at least [choose one of the following options and remove the explanation in brackets: 25 years (drug + medical device); 15 years (implantable medical device); 10 years (non-implantable medical device)] in accordance with the European clinical investigation regulation to ensure the validity of the research. This will also be the case if you stopped trial participation prematurely.

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

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

Biological samples are samples of human body material.

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

The procedure to encode your biological samples is the same as that used for your personal data in accordance with Belgian legislation on the use of human body material (see I § 12.2). Samples sent to the sponsor or to organisations working in collaboration with the sponsor, will only be labelled with your trial identification code. The sponsor ensures that the location of your biological samples is always tracked. The use of your biological samples is linked to the processing of the associated coded personal data.

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.

[Note: All biological samples used within or outside the context of a medical device clinical investigation must be registered in a Belgian biobank. These biological samples fall within the scope of the Belgian legislation on human body material].

The collection and all analyses on these biological samples, within and outside the context of this study, will always be done in accordance with the legislation on the use of human body material.

* 1. What will happen to the collected biological samples?

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

[If remainders of samples are to be **destroyed**, state here as text:] Your biological samples will be destroyed upon completion of analyses within the context of this study.

[In the case of **preservation** of samples for use within the context of the study, 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 additional research that remains within the context of the current trial and thus with the same disease or the same treatment/drug as in this study.

[If preservation of samples for use within the context of the study is optional:] You agree or disagree to the retention of the remainder of your biological samples for additional research within the context of the current trial by ticking the appropriate checkbox in Chapter II.

[In case additional samples are being collected for use within the context of the study, please add the following sentences:]

With your consent, the sponsor would also like to invite you to take part in additional that remains within the context of the current trial and thus is about the same disease or treatment/medication as in this study.

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 checkbox in Chapter II.

[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.

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

[Choose:]

Genetic analyses will also be performed on your biological samples. Genetic analyses are studies of DNA. For example, DNA determines the colour of our hair and eyes. DNA can also explain why some people respond to certain drugs and others do not. It can also explain why some people get certain diseases and others do not. The purpose of these genetic analyses is … [explain the purpose].

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.

[or]

You agree or disagree to take part in these genetic analyses by ticking the appropriate checkbox in Chapter II (on page...) The purpose of these analyses is… [explain the purpose].

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

[If no additional biological samples are being collected and if remainders of samples will be destroyed or used only within the context of the study, this paragraph 13.3 may be deleted].

[Please note that biological samples under this paragraph should be registered in a recognized Belgian biobank].

[In case of a secondary use of samples, *i.e.* in case of additional research not about the same disease or treatment/drug as this study, add the following sentences:]

[If **remainders** of biological samples will be used for additional research outside the context of this study, add the following sentence:]

You agree or disagree that the sponsor will retain the **remainders** of your biological samples for [number] years for additional research outside the context of the current trial by ticking the appropriate checkbox in Chapter II.

[If **additional** biological samples will be collected for additional research outside the context of this study, add the following sentence:]

You agree or disagree to donate **additional** biological samples and for these to be retained for [number] years for the purpose of additional research outside the context of the current trial by ticking the relevant checkbox in Chapter II.

If you agree, this additional research may only be conducted according to the legislation on the use of human tissue material and with the approval of a Belgian recognized Ethics Committee.

[In case of **genetic analyses** outside the context of the study, include the following sentences:]

You agree or disagree that genetic analyses will also be performed on your biological samples outside the context of the current trial by ticking the relevant box in Chapter II. The purpose of these analyses is ... [explain the purpose].

[If you wish to produce/obtain artificialized or extracted material from additional biological samples or remainders of biological samples solely for non-genetic research outside the context of this study, add the following paragraphs].

If you agree, the sponsor wishes to produce or culture material (e.g. cell lines or cell cultures) from your additional biological samples or remainders of your biological samples or obtain material from them that does not itself contain cells (e.g. proteins or DNA) and use this material exclusively for non-genetic research outside the context of this trial. In this case, the sponsor will break the link between your biological samples and your identity, as explained below in § 13.4.

You agree or disagree to the creation/cultivation or acquisition of material from your additional biological samples or remainders of your biological samples for exclusively non-genetic research, outside the context of this study by ticking the relevant checkbox in Chapter II.

* 1. [If applicable] Can the link between my biological samples and my identity be broken?

[If biological samples will no longer be traceable, add the following paragraphs. Removal of traceability of biological samples is only possible with the explicit consent of the donor.]

If you agree, it will no longer be possible to link your biological samples to your identity, once used in the context of this study.

As a result, it will no longer be possible to inform you of potentially meaningful information obtained from analyses on your samples.

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

You agree or disagree that after being used in the context of this study, it will no longer be possible to link your biological samples to your identity by ticking the relevant checkbox in Chapter II.

## What if the trial reveals meaningful information about your health?

We may discover new information about your health during the course of the trial. If this information may be important to your health, the sponsor will inform the researcher. With your consent, the researcher will inform you and your treating physician about your results and the possible consequences. If necessary, the researcher and/or the treating physician will advise you on what to do next.

You can let the researcher know whether you agree to be informed about meaningful information discovered about your health by ticking the relevant checkbox in Chapter II. The researcher/your treating physician will inform you about this information in any case where not being informed may cause serious harm to your health or that of third parties.

## Who has reviewed and approved the trial documents?

The documents of the trial have been reviewed by

* [If applicable: please remove evaluation by the FAMHP for PMCF clinical trials] 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.

# CHAPTER II - Informed consent

*The official title of the study for lay persons as listed in the EUDAMED database.*

[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 read this form and understood its information.
* I declare that I have been informed of and that I understand the purpose of the trial, its duration and consequences, possible risks and discomforts, the precautions that I must 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.
* [If “public interest” is chosen as legal base, use:] I am aware that my personal data is being processed as described in Chapter I, § 12.
* I understand that representatives of the sponsor, the ethics committee, and competent health authorities have access to my medical record if authorised to do so (as described in Chapter I, §12.5).
* 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).
* (If applicable) I understand the importance of contraception and will adhere to the recommendations provided. I will also inform my partner(s) about my participation in a clinical study involving a drug that may be harmful to the fetus, and we will take the necessary contraceptive measures together.
* I agree to my treating physician(s) being informed of my participation in this trial.
* If I take part in another interventional trial, I must inform the investigator or trial team about this. I agree not to take part in any other interventional trial (e.g. with a study drug, medical device, experimental surgical technique) 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 cooperateand 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 analyses will be conducted on my biological samples.
* I certify that all the information I have given about my medical history is correct, to the best of my knowledge. I understand that it may be harmful to me if I do not inform the investigator of possible reasons why I could not participate in the study.

Optional consents which are no prerequisite for your participation in this trial.

**Compensation THROUGH an external VENDOR**

1. [If compensation can be arranged through an external vendor for which personal data are collected] As mentioned in Chapter I, § 11.2, you can receive your compensation through [form of compensation through external vendor, e.g. payment card] and an external vendor, called [external vendor], will have to process some of your personal data. If you do not agree to share your personal data and/or receive your compensation through this form of compensation, the sponsor will compensate the trial site. The trial site will, in turn, compensate you at the same rates as mentioned above through [form of compensation through the study centre, e.g. bank transfer/voucher].

Do you agree to your personal data being shared with an external vendor [external vendor] for payment of your compensation via [compensation form, e.g. payment card]?

**(Tick as appropriate.)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

**DATA OBTAINED FROM THIS TRIAL**

1. [If applicable and if ‘consent’ was chosen as the legal base for data processing] As specified in Chapter I, § 12.8, the sponsor would like to be able to use your data obtained from this trial for 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.)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

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

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

As specified in Chapter I, § 13.2, the sponsor would like to conduct genetic analyses on your biological samples within the context of the trial that you will participate in.

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

**(Tick as appropriate.)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

1. [If retention of the remainders of biological samples for use for additional research within the context of the study is optional] As specified in Chapter I, § 13.2, the sponsor would like to retain the remainders of your biological samples for [number] years for additional research within the context of the trial that you will participate in.

Do you agree with the retention of the remainders of your biological samples and the accompanying personal data for additional research within the context of the trial?

**(Tick as appropriate..)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

1. [If applicable] As specified in Chapter I, §13.2, the sponsor would like to collect additional biological samples from you and retain these samples for [number] years for supplementary research within the context of the trial that you will participate in.

Do you agree to donate additional biological samples and for these samples to be retained for supplementary research within the context of the trial?

**(Tick as appropriate..)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

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

1. [If applicable] As specified in Chapter I, § 13.3, the sponsor would like to retain the remainders of your biological samples for [number] years for additional research outside the context of the study you will take part in.

Do you agree to the remainders of your biological samples and associated personal data being retained for additional research outside the context of the trial?

**(Tick as appropriate..)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

1. [If applicable] As specified in Chapter I, § 13.3, the sponsor would like to obtain additional biological samples from you and retain these samples for [number] years for additional research outside the context of the trial you will take part in.

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

**(Tick as appropriate..)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

1. [If applicable] As specified in Chapter I, § 13.3, the sponsor would like to perform genetic analyses on your biological samples outside the context of the trial you will take part in.

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

**(Tick as appropriate..)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

1. [If applicable] As specified in Chapter I, § 13.3 the sponsor would like to produce or culture material (e.g. cell lines or cell cultures) from your additional biological samples or remainders of your biological samples, or obtain material from them that does not itself contain cells (e.g. proteins or DNA) and use this material exclusively for non-genetic research outside the context of this trial.

Do you agree to the creation, cultivation or acquisition of material from your additional biological samples or remainders of your biological samples for exclusively non-genetic research outside the context of this trial?

**(Tick as appropriate..)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

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

1. [If applicable] As specified in Chapter I, § 13.4, the sponsor would like to break the link between your biological samples and your identity once they have been used in the context of this study.

Do you agree that your biological samples can no longer be linked to your identity once used in the context of this study?

**(Tick as appropriate.)**

|  |  |
| --- | --- |
| [ ]  **I agree**  | [ ]  **I do not agree**  |

**MEANINGFUL INFORMATION**

1. As specified in Chapter I, §14, it may occur that meaningful information is discovered that may be important for your health or that of third parties.

If this were to occur, would you like the researcher/your treating physician to inform you of this result?

**(Tick as appropriate.)**

|  |  |
| --- | --- |
| [ ]  **No, I do not wish to be informed.**  | [ ]  **Yes, I wish to be informed.** |

I consent to take part in the trial, [if optional questions must 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. [[5]](#endnote-6))

I declare that I have been informed that I am being asked to take a decision on whether to take part in the 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 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. [[6]](#endnote-7) )

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/interpreter, 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 on trials.

[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 the abbreviations and terms perhaps difficult to understand for the non-medically educated participant. Any abbreviations should be written in full in the text when used for the first time.]

FAMHP: Federal agency for medicines and health products

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

Other abbreviations that appear in the text:

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 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 entire process of the trial. The auditor performs an independent, one-time quality check at some time during the trial. They verify if the trial is being/was conducted according to the protocol if the reported data are liable and if the trial was conducted according to 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. [↑](#endnote-ref-2)
2. In accordance with Article 74 of Regulation 536/2014 and Article 12, §2 of the Belgian Law of 7 May 2017 on clinical investigations for medicinal products for human use, the sponsor or a legal representative of the sponsor must be based in the European Union. [↑](#endnote-ref-3)
3. Throughout the document, the term ‘’encoding‘’ is used as a synonym for ‘’pseudonymisation‘’, the term used in General Data Protection Regulation No 2016/679. [↑](#endnote-ref-4)
4. If the sponsor wishes to use the data for FDA, this sentence must be included in the ICF (CFR 50.25(c)) as described in the directive [(https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm291085.pdf](file:///%5C%5C%5C%5Chealth.fgov.be%5C%5Cshares%5C%5CDGGS%5C%5CCTR_College%5C%5C6_Application_dossier%5C%5CICF_template_BAREC_MDR%5C%5C%28https%3A%5C%5Cwww.fda.gov%5C%5Cdownloads%5C%5Cregulatoryinformation%5C%5Cguidances%5C%5Cucm291085.pdf)). [↑](#endnote-ref-5)
5. When a person of full age is incapable of expressing his will, legal representation must be used which is determined in successive order (person whom the patient has previously designated to act in his place, administrator, or failing that, cohabitating spouse, the legal cohabiting partner, de facto cohabiting partner, an adult child, a parent, an adult brother or sister). If that person does not wish to do so or is absent, the professional concerned, where appropriate in multidisciplinary consultation, represents the interests of the patient. The regulation is laid down in article 31 of the law of 7 May 2017 on experiments on the human person and articles 12 and 14 of the Law of 22 August 2002 on patients’ rights. [↑](#endnote-ref-6)
6. The use of an impartial witness is necessary when the subject or their legal representative speaks and/or fully understands the language of the approved informed consent form but cannot read and write due to a physical disability or is visually impaired. An interpreter is necessary when the investigator does not speak the patient's language. [↑](#endnote-ref-7)