Instructions for the proper use of the model Informed Consent Form

Format of the ICF[1]

The Ethics Committees opt for a format for the informed consent form in 3 parts:

1. the **information** essential to the decision to take part:
   This part must contain all the information essential to the decision-making process of the participant, such as
   a. a brief, clear presentation of the rights of the participant (voluntary participation; confidentiality; insurance, etc.)
   b. a clear description of the research project (context, objectives, methodology & course).
   c. descriptions of the risks & benefits.
2. **consent**;
3. **supplementary information** (appendices) that gathers together information that does not fall directly within the decision-making process but which includes
   a. useful information such as the number, frequency and content of each of the visits scheduled in the methodology,
   b. more detailed information on participants' rights

Editorial aspects

The ICF must be worded such that it can be read and understood by people who are not health-care professionals, who have not received verbal information and which potential participants may wish to consult (family, spouse, etc.).

The ICF must be written in a **language that is clear and understandable** for the participant:

a. **Structured** information, clear thread;
b. Correct sentence structure (attention to problems of literal translation from English to French/Dutch, inappropriate choice of terms, etc.);
c. Short sentences, language understandable for most of the participants at whom the document is directed.
d. No professional jargon;
e. Use the same terminology throughout the document for the same concept (example: do not refer to study then research then clinical trial).
f. Avoid the over-use of abbreviations.
g. No spelling mistakes;
h. Sufficiently large font size (reference: ≥ Arial 10), especially when the probable reader of the ICF is likely to have sight problems.

Administrative requirements

1. The 3 parts of the document, namely the information for the participant/legal representative, the consent and the appendices form a single document and are therefore identified by the same version number and the same date of issue.
2. Each part will include the full title of the study in the original language of the document.
3. The pagination of the whole document will be presented in the format "page X/Y".

Specific site adaptation: Replace the sequence information – consent – appendices by information – appendices – consent.

[1] In the template, the text in red refers to instructions, draw attention to alternatives or propose a comment to the author of the document. The text in black suggests wordings we would like to see in the finalised ICF. The blue text indicates what must be addressed.

Title of the study: Official title in English and simplified version understandable for participants

Sponsor of the study: *Name and address of the enterprise, hospital, university or other organisation; Name and address of CRO*

Medical Ethics Committee: *Identification of the Ethics Committee that issued the single opinion on the trial and the local Ethics Committee that took part in the approval process.*

Local investigators: *Name, affiliation and contact details*

I Information vital to your decision to take part (4 pages)

Introduction

You are being invited to take part in an observational clinical study. This means that the treatment you have been offered was prescribed in the usual manner, in accordance with the conditions of good medical practice and independently of your possible participation in this study.
We are simply asking you whether we can collect data from your medical records to be able to combine them with those of other patients receiving the same treatment and to process them statistically for research purposes.
No additional diagnostic or monitoring procedure will be proposed.

[Or] Apart from a few questionnaires we will ask you to complete, no additional diagnostic or monitoring procedure will be proposed.

Before you agree to take part in this study, we invite you to take note of its implications in terms of organisation, possible risks and benefits, to allow you to make a decision with full awareness of the implications. This is known as giving “informed consent”.

Please read these few pages of information carefully and ask any questions you want to the investigator or his/her representative.

There are 3 parts to this document: the information essential to your decision, your written consent and supplementary information (appendices) detailing certain aspects of the basic information.

If you take part in this study, you should be aware that:

- The treatment offered to you by the investigator in accordance with current recommendations will not be altered if you take part in the study.
- This clinical study is being conducted after having been reviewed by one or more ethics committees.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, you can stop taking part by informing the investigator.
- The data collected on this occasion are confidential and your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You may contact the investigator or a member of his/her team at any time should you need any additional information.

Further information about your “Rights as a participant in a clinical study” can be found in appendix XX.

Objectives and course of the study

This clinical study has been organised to ….description of objectives in a few lines.

We are inviting you to take part in this clinical study because your doctor has offered you (describe the treatment) within the context of your clinical situation.

This clinical study is to include (number) patients, including approximately (number) in Belgium.

To be able to take part in this study you must …describe the inclusion/exclusion criteria for participants.

Your participation in the study will last the length of a single consultation, during which your doctor will ask you questions to gather all the data and information required for the study, such as your demographic data (age, weight, height, gender) as well as data concerning your medical history, your medication use, your diet, your addictions (smoking habits, alcohol consumption) … etc. (to be developed depending on the studies).

[Or] Your participation in the study will last around x months/years, during which, at each consultation visit proposed by your doctor, we will ask your doctor to send us information related to your treatment, to the progression of your clinical situation and your symptoms and the results of the prescribed examinations (specify … medical imaging examinations, biological examination, etc.).

[Depending on the studies] Your doctor will also ask you to complete several questionnaires to assess … (specify: your quality of life, your level of anxiety, etc…avoid using names of questionnaires that do not tell the patient anything)

Completing these questionnaires will take you x minutes during each consultation/during one of the annual consultations (specify)

Description of risks and benefits

As indicated above, neither the treatment that has been proposed nor the diagnostic and monitoring procedures for your clinical situation go beyond good medical practice. No risk, in terms of health, can be linked to your participation in this study.

Similarly, you should not expect any personal benefits as a result of taking part in the study. Know only that your participation will allow us to better understand … specify and thus to offer better treatments in the future.

Withdrawal of consent

Your participation is voluntary and you are entitled to withdraw your consent to take part in the study for any reason, without having to justify your decision.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

[If applicable] The sponsor/party responsible for the study may also decide to stop the study because the data collected provide a faster response than originally expected.

If you take part in this study, we ask you:

- To cooperate fully in the smooth running of this study.
- Not to conceal anything such as information relating to your state of health, the medication you are taking or the symptoms you are experiencing.
- To inform your doctor if you are asked to take part in another study to discuss with him/her the possibility of taking part in this study and to see whether you should then stop taking part in the present study.
- etc… such as the possible need for investigator/GP contact for the gathering of additional information when appropriate

Contact

If you need further information, but also if you have problems or concerns, you can contact the investigator (Surname, First name) or a member of his/her research team (Surname, First name) on the following telephone number

If you have any questions relating to your rights as a participant in a clinical study, you can contact the patient rights ombudsman[2] of your institution on this telephone number: telephone details. If necessary, he/she can put you in contact with the ethics committee.

[2] For trialsinvolving patients recruited outside of a hospital environment (trials in medical practices, non-hospital phase 1 research units), there is no reason to contact the patient rights ombudsman … in this case mention that the ethics committee may be contacted.

Title of the study: Official title in French and simplified version understandable for non-experts

II Informed consent (1 to 2 pages)

Participant

I declare that I have been informed of the nature of the study, its purpose, its duration, the possible side effects and what is expected of me. I have taken note of the information document and the appendices to this document.

I have had sufficient time to think about it and discuss it with a person of my choice (GP, relative).

I have had the opportunity to ask any questions that came to mind and have obtained a favourable response to my questions.

I understand that data about me will be collected throughout my participation in this study and that the investigator and the sponsor of the study will guarantee the confidentiality of these data in accordance with applicable European and Belgian legislation.

I agree to my personal data being processed as described in the section dealing with confidentiality guarantees (page x/y). I also consent to these data being transferred to and processed in countries other than Belgium.

[Depending on the studies] I agree/do not agree (delete as appropriate) to the research data collected for the purposes of this study being processed at a later date provided this processing is limited to the context of the present study (better understanding of the disease and its treatment).

[Depending on the studies] I agree/do not agree (delete as appropriate) to my GP or other specialists in charge of my health being contacted if required to obtain additional information about my health.

I have received a copy of the information to the participant and the informed consent form.

Surname, first name, date and signature of the volunteer.

[If a witness/interpreter is present.] **Witness/Interpreter**

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

Surname, first name and qualification of the witness/interpreter:

Date and signature of the witness/interpreter.

Investigator

I, the undersigned, [surname, first name] investigator/clinical research assistant, confirm that I have verbally provided the necessary information about the study and have given the participant a copy of the information document.

I confirm that no pressure was applied to persuade the patient to agree to take part in the study and that I am willing to answer any additional questions if required.

I confirm that 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 of 7 May 2004 related to experiments on humans.

Surname, first name, date and signature
of the investigator's representative

Surname, first name, date and signature
of the investigator

Title of the study: Official title in French and simplified version understandable for non-experts

III Supplementary information

1: Supplementary information on the organisation of the study

This appendix will include a brief description of the various follow-up consultations that form part of the "standard of care" and where appropriate the various examinations normally scheduled during these consultations.

2. Supplementary information on the risks associated with participation in the study: not applicable

In principle, this section does not apply in an observational study: the treatment and examinations proposed in the clinical follow-up are prescribed in accordance with the conditions of good clinical practice. They are therefore presented to patients in accordance with the information obligations in the context of doctor/patient interaction and independently of any participation in the study.

If the sponsor decides to nevertheless present them, it must **then insist** on the fact that all that is mentioned in this section are the risks incurred in the context of standard care (and notably not covered by the study insurance!)

3: Supplementary information on the protection and rights of the participant in a clinical study

Ethics Committee

This study has been reviewed by an independent Ethics Committee, namely the Ethics Committee of [Name of EC], which has issued a favourable opinion [*after consulting with the Ethics Committees of each centre where this trial will be conducted*]. It is the task of the Ethics Committees to protect people who take part in a clinical trial. They make sure that your rights as a patient and as a participant in a clinical study are respected, that based on current knowledge, the study is scientifically relevant and ethical.
You should not under any circumstances take the favourable opinion of the Ethics Committee as an incentive to take part in this study.

Voluntary participation

Before signing, do not hesitate to ask any questions you feel are appropriate. Take the time to discuss matters with a trusted person if you so wish.

Your participation in the study is voluntary and must remain free of any coercion: this means that you have the right not to take part in the study or to withdraw without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the investigator or the quality of your future therapeutic care.

If you agree to take part in this study, you will sign the informed consent form. The investigator will also sign this form to confirm that he/she has provided you with the necessary information about the study. You will receive a copy of the form.

Costs associated with your participation

The sponsor has arranged to compensate the hospital for the time devoted to the study by the investigator and his/her team. You will not receive any compensation for your participation in this study. Furthermore, the study will not involve any additional costs for you.

Guarantee of confidentiality

Your participation in the study means that you agree to the investigator collecting data about you and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

Your data will be processed in accordance with the European General Data Protection Regulation (GDPR) and with the Belgian legislation on the protection of natural persons with regard to the processing of personal data. [NAME] shall act as data controller for your data.

You are entitled to ask the investigator what data are being collected about you and what is their use in connection with the study. This data concerns your current clinical situation but also some of your background, the results of examinations carried out within the context of care of your health in accordance with current standards. You have the right to inspect these data and correct them if they are incorrect[3].

The investigator has a duty of confidentiality vis-à-vis the data collected.

This means that he/she undertakes not only never to reveal your name in the context of a publication or conference but also that he/she will encode your data before sending them to the manager of the database of collected data (**to be identified:** name of the department acting as data manager, name of sponsor, location).

The investigator and his/her team will therefore be the only ones to be able to establish a link between the data transmitted throughout the study and your medical records[4].

The personal data transmitted will not contain any combination of elements that might despite everything allow you to be identified[5].

For the study data manager designated by the sponsor, the data transmitted will not allow you to be identified. The latter is responsible for collecting the data gathered by all investigators taking part in the study, processing them and protecting them in accordance with the requirements of the Belgian law on the protection of privacy.

To verify the quality of the study, it is possible that your medical records will be examined by third parties (ethics committee, representatives of the study sponsor, external auditors). In any event, this may only take place under the responsibility of the investigator or of one of his/her colleagues and by persons subject to the obligation of professional secrecy.

These (encoded) data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organisations working in collaboration with the sponsor.

They will also be able to be sent to other sites of the sponsor in Belgium and in other countries where the standards in terms of the protection of personal data may be different or less stringent[6].

Your consent to take part in this study therefore also implies your consent to the use of your encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities.

The sponsor undertakes only to use the data collected within the context of the study in which you are taking part.

[Or where applicable] The sponsor will use the data collected within the context of the study in which you are taking part, but would also like to be able to use them in connection with other research concerning the same disease as yours and its treatment. Any use of your data outside the context described in this document is only possible with the approval of the ethics committee.

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3 These rights are guaranteed by the European Data Protection Regulation (GDPR), by the Belgian legislation on the protection of natural persons with regard to the processing of personal data and by the Law of 22 August 2002 on patient rights.

4 For clinical studies, the law requires this link with your records to be retained for 20 years.

5 The database containing the results of the study will therefore not contain any combination of elements such as your initials, your gender and your full date of birth (dd/mm/yyyy).

6 The sponsor then undertakes to respect the constraints of the European General Data Protection Regulation (GDPR) and the Belgian legislation on the protection of natural persons with regard to the processing of personal data.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

If you have any questions relating to how your data are being processed, you may contact the investigator. The data protection officer in your hospital can be contacted as well: ~~DPO - UZ Leuven, Herestraat 49, 3000 Leuven, e-mail dpo@uzleuven.be~~. (please mention the contactdetails of the site specific DPO)

Finally, if you have a complaint concerning the processing of your data, you can contact the Belgian supervisory authority who ensures that privacy is respected when personal data are processed.

The Belgian supervisory authority is called:
Data Protection Authority (DPA)
Drukpersstraat 35,
1000 Brussels
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: https://www.dataprotectionauthority.be

Insurance

In an observational study, the only possible risk would be a flaw in the measures taken to protect the confidentiality of the private information about you. Even without fault, the sponsor accepts responsibility for damage caused to the participant (or his/her dependants) and linked directly or indirectly to participation in this study. In this context, the sponsor has taken out an insurance contract (name of the insurance company, policy number, contact details)[7].

[7] In accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004)