

Instructions¹ for the proper use of the model Informed Consent Form

Format of the Informed Consent Form (or “ICF”)²

The Ethics Committees opt for a format for the informed consent form in 3 parts and limited to around fifteen pages:

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, inclusion/exclusion criteria, methodology & course) highlighting the constraints in addition to the standard treatment (outside the study),
 - c. descriptions of the risks & benefits and presentation of the measures taken to minimise the risks,
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. additional information to that presented in the first part, such as the details of the risks associated with the study procedures;
 - c. more detailed information on participants’ rights.

Editorial aspects

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

Please take note of the following advices:

- a. Use the correct sentence structure (pay attention to problems of literal translation from English to French/Dutch, inappropriate choice of terms, etc.);
- b. Use short sentences (less than 12 words) and short paragraphs (less than 7 lines). Use bullet points where possible.
- c. Avoid technical jargon.
- d. Use the same terminology throughout the document for the same concept (example: do not refer to study then research then clinical trial).
- e. 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.
- f. Use a clear and sufficiently large font size:
 - i. when printing on A4 in one or two columns, preferably use a font size \geq Arial 12;
 - ii. when printing in booklet format, the margins should be reduced and the font size increased to \geq Arial 16.
- g. Use an attractive design with sufficient (sub)titles and white rules.
- h. If possible, involve a patient or patient association in the development of the ICF (in relation to comprehensibility, relevance of information).
- i. All pages of the document should be identified by the same version number of the ICF and the same date of issue.

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.

² This template ICF template was developed for interventional studies that are not clinical trials. Clinical trials are interventional studies with drugs and there is a separate template ICF template for interventional clinical trials with study drug in adult patients for this purpose. Certain wording needs to be adapted, e.g. in the context of questionnaire studies, additional procedures such as a blood sampling, scans, tests, comparison of techniques, etc. In the model, footnotes printed in red at the bottom of the page again point this out.

- j. Some wordings should be adapted according to the study. Please take into account that some paragraphs may not be applicable such as, for example, the mention of medical records or disease in the case of a study with healthy volunteers.

Administrative requirements

1. The 3 parts of the document, namely the information for the participant/legal representative, the consent and the supplementary information (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.

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;*

Research 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 (5 pages)

Introduction

You are being invited to take part in a study to evaluate *(to be completed according to the type of investigation)*. The aim is *(to be completed)*.

Participation in the study may or may not be beneficial for you. There is, however, no guarantee that you will benefit from taking part in this study.

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 clinical study, you should be aware that:

- This clinical study is being conducted after having been reviewed by one or more ethics committees *(adapt to what is applicable)*.
- 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. *Your decision not to take part or to stop taking part in the study will have no impact on the quality of your care or on your relationship with the investigator/treating physician(s) (where applicable)*.
- 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 will not incur any charges for the visits/consultations, examinations or treatments specific to this 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 description of the study protocol

We are inviting you to take part in a clinical study to evaluate *(specify)* that is to include around *(number)* participants, *(where applicable)* including approximately *(number)* in Belgium. *(where applicable) (specify)* is a disease in which ... *(briefly explain the disease in at least 5 sentences)*.

Describe the objectives in a few lines and indicate the main inclusion criteria as set out in the protocol.

Description of the study design in terms understandable to the participant.

Course of the study

Your participation in the study will last around *(x)* weeks/months and involve *(y)* visits.

Description of the tests, treatments and examinations (this may include completing questionnaires, additional blood collection, performing tests, comparing techniques...) that one wishes to perform as part of this study. Please specify the duration. Preferably in table form.

Risks and discomforts

A: Side effects of the tests, treatments and examinations

Describe the possible risks/discomforts of the tests, treatments and examinations (severity, duration, impact on daily life,...).

Other currently unknown risks and discomforts could appear. It is therefore very important that any new health problem is quickly reported to the investigator, regardless of whether or not you think it has to do with the study.

[Where applicable] B: Interaction with medicines or other interactions

Provide relevant information on warnings, interactions, precautions or contraindications related to the tests, treatments and examinations.

C: Risks associated with the procedures of the clinical study

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

X-ray

MRI

Biopsy

etc.

[Where applicable] D: Contraception, pregnancy and breast-feeding

Female participant: Because the effects of (specify) on an unborn child or infant are not properly known, you will not be allowed to take part in this study if you are pregnant, wish to become pregnant or if you are breast-feeding.

If you choose to take part in this study, you must use one of the authorised methods of contraception (so that you do not become pregnant). Your investigator will discuss the various appropriate options with you, as described in the appendix (Appendix XX).

Male participant: Include brief information concerning the risks or absence of risks for the partner of a male participant in the clinical study.

[Example in case of risk] The tests, treatments and examinations used in the study could lead to an unknown risk for an embryo or foetus. For this reason it is important that your partner does not become pregnant for the duration of the study and up to < 3 months > after the the tests, treatments and examinations (adapt if necessary). You undertake to inform your partner of your participation in this study and of the potential risk to an embryo or foetus.

If a pregnancy occurs, the investigator must be notified immediately.

If the partner of a male participant becomes pregnant, the participant should be motivated to inform the investigator to allow the best option to be chosen for her and the foetus/baby, an option that may involve this pregnancy being included in a monitoring programme.

The collection of personal health data (progress of the pregnancy, birth and first months of life of the child where applicable) must be subject to the express consent of the pregnant partner. This 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).

[Where applicable] Notification of new information

It may be that during the course of a clinical study, important new information on the tests, treatments and examinations becomes available. You will be informed of any new element that might affect your decision to continue taking part in this study.

In this case, you will be asked to sign either an addendum to the consent form or a new informed consent form. If, in the light of the new information, you decide to stop taking part in the study, your investigator will see to it that you continue to receive the best possible treatment.

Benefits

If you agree to take part in this study, (specify) may or may not be beneficial for you.

The information obtained thanks to this study may contribute to a better knowledge of (specify) for the treatment of (disease/condition) in future patients.

[Or] 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.

[Where applicable] Alternative treatment

Other treatments are available for your condition. Specify in one or two lines.

The investigator will discuss these treatments with you in detail.

Withdrawal from the study

Your participation is voluntary. You are entitled to withdraw from the study for any reason, without having to justify your decision. Nevertheless, it may be useful for the investigator and for the sponsor of the study to know if you are withdrawing because the constraints of the tests, treatments and investigations are too great (too many uncomfortable side effects, for example).

It is also possible that the investigator withdraws you from the study because he/she thinks it is better for your health or because he/she finds out that you are not following the instructions given to participants.

Finally, the ethics committees that initially approved the study or the sponsor may break off the study because of health reasons.

Treatment after stopping the study

In all these situations of withdrawing from the study, but also when the scheduled participation period has ended, your investigator will assess your state of health and prescribe the best treatment available.

[Or] The investigational tests, treatments and examinations will be able or not be able to be supplied to you after your participation in this research because ...justify.

[Adapt depending on the study] If you take part in this study, we ask you:

- To cooperate fully in the smooth running of this study.
- Not to conceal any information relating to your state of health, the medication you are taking or the symptoms you are experiencing.
- To contact the investigator if you wish to participate in another clinical trial.

[Where applicable] You should also be aware that:

your GP, if you have one, or other specialists in charge of your health will be informed of your participation in this study.

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 (+32 xxx-xx-xx) or by e-mail (e-mail address).

If you have any questions relating to your rights as a participant in a study, you can contact the participant rights ombudsman of your institution on this telephone number: telephone details³. If necessary, he/she can put you in contact with the ethics committee.

[If patients are included] In case of emergency, you can contact XX on the following telephone number XX.

Outside consulting hours, contact the A&E department of your hospital, indicating that you are taking part in a clinical study. Your records will contain information of use to the on-call doctor in relation to this clinical study.

³ For trials involving patients recruited outside of a hospital environment (trials in medical practices,), 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 English 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, any risks and benefits 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, such as my GP or a member of my family.

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 study is voluntary and that I am free to end my participation in this study (**where applicable**: without this affecting my relationship with the therapeutic team in charge of my health).

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.

[If "consent" is chosen as the legal basis, use:] I agree to my personal data being processed as described in the section dealing with confidentiality guarantees (appendix **XX**). I also consent to these data being transferred to and processed in countries other than Belgium.

[If "consent" is chosen as the legal basis, you can use the following:]

[Depending on the studies] I agree/do not agree (delete as appropriate) to the study 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 for a better understanding of the disease and its treatment.

[Depending on the studies] I agree/do not agree (delete as appropriate) to the sponsor retaining samples of biological material collected during the study **for x years** for subsequent research purposes but limited to the context of the present study.

[Depending on the studies] I agree to my GP or other specialists in charge of my health being informed of my participation in this clinical study.

As described in the section titled "Incidental findings", incidental findings may arise that may be relevant to your health or the health of your blood relatives.

I agree/I do not agree (strike out what does not apply) that the researcher should inform me (directly or through my treating physician) of this result.

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 the study may include incapable persons.] Legal representative

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

[In situations where the incapacity is temporary.]

I have also been informed that as soon as the clinical situation allows, the person I represent will be made aware of his/her participation in a clinical study 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 copy of the information to the participant and the informed consent form.

Surname, first name and relationship to the person represented:

Date and signature of the legal representative.

[I a witness/interpreter is present.] Witness/Interpreter

I was present during the entire process of informing the participant 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 study 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 participant 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 English and simplified version understandable for non-experts

III Supplementary information (7 to 9 pages)

1: Supplementary information on the organisation of the study

Depending on the studies, it may be useful to provide the participant with a detailed plan of the various procedures he/she will be required to undergo at each of the scheduled visits.

A summary flow-chart allowing a correct distinction to be made between routine procedures and visits/consultations (SC for standard of care), the results of which may be used in the study, and visits and procedures specific to the study (SS), and therefore charged to the sponsor, should be proposed.

This appendix will also include a description of the scheduled examinations, any precautions to be taken before undergoing these examinations

2: Supplementary information on the protection and the 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 in Belgium 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 participant in a clinical study are respected, that based on current knowledge, the balance between risks and benefits remains favourable to the participants, that 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.

However, it is advisable to inform the investigator if you have decided to stop taking part in the study.

If you agree to take part, 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 participation⁴

The sponsor has arranged to compensate the hospital for the time devoted to the study by the investigator and his/her team, for the consultations specific to the study and for all examinations scheduled in connection with this study.

(Where applicable) Similarly, the investigational treatment (eg food supplement, provision of an application) will be paid for by the sponsor.

If you decide to take part in this study, this will not therefore involve any extra costs for you or your insurer. The visits and procedures identified as specific to the study in the description of the course of the study on page x1 to x2/y or in the table on page x/y will be paid for by the sponsor. (Where applicable) You may only be charged for the costs corresponding to the standard medical care in your clinical situation.

[Or] If you decide to take part in this study, all the examinations or procedures necessary for the study will be paid for by the sponsor.

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

⁴ Please consult BAREC's guidelines on reimbursing participants on their website <https://barec.be/>.

Type	Amount
Travel costs, public transport, parking	[number] EUR per visit, [number] EUR per kilometer, reimbursement of fee
Meals	[number] EUR per visit
Medication needed to treat side effects	Reimbursement of patient's cost
Study specific contraception, sun cream, etc	Reimbursement of actual patient's cost, fixed amount
Time investment and efforts	[number] EUR per visit / trial
...	

[The sponsor has to inform the participant about the following:

- The different reasons for compensation and what amount of compensation for each category is offered. Please use the table above.
- The form of compensation (bank transfer, vendor, etc) has to be defined including alternative options.
- The timing and conditions of payments.]

Guarantee of confidentiality

Your participation in the study means [If "consent" is chosen as the legal basis: 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.

The processing of your personal data in this study is authorised because it is necessary for scientific research purposes and ...

[The sponsor is obliged to choose the legal basis. Note that the choice you make involves obligations and consequences for the sponsor. Your choice must comply with Belgian and European legislation].

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 of the sponsor] 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 the current standards and obviously the results of examinations required by the protocol. You have the right to inspect these data and correct them if they are incorrect⁵.

Please adjust the information given in the paragraph above if this would not be applicable as, for example, in a study with healthy volunteers. In some clinical trials, this right of access may be postponed to the end of the study to avoid creating bias in the study. This must then be explained to the participant.

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 pseudonymise (your identity will be replaced by an ID code in the study) 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 records⁶.

⁵ These rights are guaranteed by the European Data Protection Regulation (GDPR), by the Belgian legislation of 18 July 2018 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.

⁶ For clinical trials, the law requires this link with your records to be retained for 20 years. In the case of a advanced therapy medicinal product using human biological material, this period will be a minimum of 30 years and a maximum of 50 years in accordance with the Belgian Law of 19 December 2008 on the use of human biological material and the applicable royal decrees.

The personal data transmitted will not contain any combination of elements that might allow you to be identified⁷.

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 persons subject to professional secrecy and designated by the ethics committee, the sponsor of the study or an independent audit body. In any event, this examination of your medical records may only take place under the responsibility of the investigator and under the supervision of one of the collaborators designated by him/her.

The (pseudonymised) study data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other investigators 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? As explained above, the transmitted data are pseudonymised.

Your consent to take part in this study therefore also implies [If "consent" is chosen as the legal basis: that you agree: your consent to] the use of your pseudonymised 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. Any use of your data outside the context described in this document is only possible with the approval of the ethics committee.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data pseudonymised 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: ([contact details](#)).

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>

[Where applicable] **What happens to your sample/samples during and after the study?**

The sponsor of the study undertakes that the samples will only be used within the context mentioned in this section.

1) Samples collected as part of this study

⁷ 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).

The sample encoding procedure is the same as that used for your medical data. Samples sent to the sponsor will therefore only include your study ID code. The sponsor is responsible for ensuring the traceability of your biological samples.

The manager of these samples (name of department/company acting as manager of this biobank of biological material for the study sponsor and its location) undertakes to use them as described in this section and to destroy them at the end of the scheduled storage period.

The sample of biological material taken is deemed to be a “donation” and you should be aware that, in principle, you will not receive any financial benefit (royalties) associated with the development of new therapies derived from the use of your donation of biological material and which may be of commercial value.

If you withdraw your consent to take part in the study, you can ask the investigator to have those of your samples that have not yet been used destroyed. The results obtained from your samples before you withdraw your consent remain the property of the study sponsor.

2) Reminders of biological samples

The sponsor shall use the biological samples within the context of the trial as described above. The surplus of your samples will be destroyed once the analyses described in this document have been carried out, i.e. in principle in X months/years.

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

Since technical progress in this area is constant, if you agree, we would like to retain the surplus of your samples of biological material for x years for future studies in the context of the present clinical research, namely a better understanding of the disease, its treatment and the responses to this treatment. Any research outside the context described in this document may only be conducted with the approval of an ethics committee.

[Where applicable] 3) Samples collected for additional research

With your consent, we would also like to invite you to take part in additional studies intended to a better understanding of the development of the disease and its treatment. Your participation in this additional research is optional and will involve donating biological material (specify). We will provide you with information specific to this research and ask you to sign a consent form specific to this additional research.

What happens in case of incidental findings?

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

Insurance

Any participation in a clinical study involves a risk, however small it is. Even if there is no fault, the sponsor accepts responsibility for damage caused to the participant (or in the event of death, his/her dependants) and directly or indirectly linked to his/her participation in the study. The sponsor has taken out insurance for this responsibility⁸.

[Where applicable] You are therefore asked to report any new health problem to the investigator. He/she will be able to provide you with additional information concerning possible treatments.

[Or] You are therefore asked to report any new health problem to the investigator before consulting another doctor, taking any other medication or receiving any other medical treatment. If, for any reason, you consult another doctor during this clinical study, you must inform him/her that you are taking part in a clinical study/present your clinical study participant card. This could be important in establishing a diagnosis and treating your complaints.

[Paragraph only applicable if patients are included] If the investigator believes that a link with the study is possible (the insurance does not cover the natural progression of your disease or the known side effects of your normal treatment), he/she will inform the study sponsor, which will initiate the

⁸ In accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004)

declaration procedure to the insurance company. The latter will appoint an expert - if it considers it necessary - to assess whether there is a link between your new health problems and the study.

In the event of disagreement either with the investigator or with the expert appointed by the insurance company and also whenever you feel it is appropriate, you or - in case of death - your dependants may bring proceedings against the insurer directly in Belgium ([name of insurance company, policy number, contact](#)).

The law provides that the insurer may be summoned to appear either before the judge of the location where the event giving rise to the damage occurred, or before the judge of your domicile, or before the judge of the insurer's registered offices.