### Instructions1 for the proper use of the model informed consent form for a case report

### Format of the ICF1 for a case report

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 patient, such as

* 1. a brief, clear presentation of the rights of the patient (voluntary participation; confidentiality; insurance, etc.)
	2. a clear description of the research project (context, objectives, methodology & course).
	3. descriptions of the risks & benefits.
1. **consent**;
2. **supplementary information** (appendices) that gathers together information that does not fall directly within the decision-making process but which includes
	1. useful information such as the number, frequency and content of each of the visits scheduled in the methodology,
	2. more detailed information on patients’ rights

**Editorial aspects**

The ICF must be written in layman's terms so that it can be read and understood by people without any professional medical background, and without receiving verbal information.

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

* 1. **Structured** information, a clear common thread;
	2. Correct sentence structure (attention to problems of literal translation from English to French/Dutch, inappropriate choice of terms, etc.);
	3. Short sentences, understandable language for the patient to whom this document is addressed
	4. No professional jargon;
	5. Use consistent terminology throughout the document for the same concept (example: do not refer to study then research then clinical trial).
	6. Abbreviations should be avoided as much as possible, and if necessary, all used abbreviations should be explained in a glossary.
	7. No spelling mistakes;
	8. Sufficiently large font size (reference: ≥ Arial 12), especially when the probable reader of the ICF is likely to have vision problems.
	9. It should be clear that this case report will be conducted within a KU Leuven Department or the UZ Leuven hospital. Therefore, the information letter and consent forms should contain either the KU Leuven or UZ Leuven header (depending on where the report will be conducted).

**Remark:**  The consent form will be signed and dated in duplicate by both the investigator and the patient, leaving one copy for each of them.

Title of the case report: Official title in English and simplified version understandable for non-experts

Sponsor of the study: *UZ Leuven*

Medical Ethics Committee: *Ethics Committee Research UZ / KU Leuven and Identification of the local Ethics Committee that took part in the approval process.*

Local investigators: *Name, affiliation and contact details*

 **I** Essential information before you decide to participate in this case report (4 pages)

**Introduction**

With this letter, we would like to ask you to consider giving Dr. **[name]** consent to process and use relevant images and/or (medical) data, that have already been collected during your standard treatment, **[delete as appropriate]** to assemble a case report regarding **[to specify: medical condition]**.

In a case report, a physician reports - in the form of a (medical) scientific article or presentation - about one, or sometimes a few, uncommon patient(s). The topic of such reports are mainly rare adverse reactions, rare diseases or congenital anomalies. More common adverse reactions and diseases are mostly analyzed and described in large clinical trials. Because of the rarity of your case, it is not possible to find multiple matching patients.

**[Explain why this patient is selected for the case report]**

To allow you to make a thoughtful decision on your participation in this case report, more information on the risks/benefits, objectives, etc. is provided below. Please take your time to go through this information and let us know if there are any uncertainties. This process is called “informed consent”.

**If you give consent, you should be aware that:**

* The application for the case report was reviewed and approved by the Ethics Committee Research UZ/KU Leuven. The main task of the Ethics Committee is to protect patients. This favorable opinion of the Ethics Committee should never been interpreted as an incentive to take part in this case report. Your participation is voluntary and must remain free from any coercion. Written consent must be obtained before you can be included in this case report. Even after providing written consent, you can still withdraw from the case report, without any reason, by informing the investigator. However, once the case report is published and/or presented, it is no longer possible to withdraw your consent. Please do not hesitate to ask all your questions. You can also discuss your participation with a confidant (like a family member or friend). You should take your time to go through all essential information before signing this document.
* All data, collected for this case report, will be kept confidential and your identity will be protected when results are published or presented.

Your data will be pseudonimized (your identity will be replaced by a code).

* This data was earlier collected in clinical research or in the standard care. It concerns data regarding (i) your current clinical situation, but also (ii) your medical history and (iii) the results of examinations carried out to treat your disease **[to specify]** in accordance with current standards of care **[specify as much as possible for case report]**. No new data will be collected for this case report.
* In case you would like to receive additional information, you can always contact the investigator or a member of his/her team.

**Objectives and course of a case report**

Case reports are typically used to share information between physicians about patients during their follow-up. This information will be published, in a printed or online format, in medical journals or can be presented on scientific conferences. The main objective of case reports is to inform colleagues.

We will use the following information for this case report: **[to complete: specify which data and images will be used.]**

**Description of risks and benefits**

There are no health related risks regarding your participation to this case report.

Similarly, you should not expect any personal benefits following your consent.

Your consent to process your data, will allow us to better understand **[specify the medical condition]** and thus to offer better treatments in the future.

Because case reports describe data from merely one or a few patients with rare diseases like **[specify the medical condition]**, a slight risk for a breach in the confidentiality and protection of your data exists. Such data breaches will be strongly avoided at all times. In this regard, the physician and his/her team will be perpetually subject to the obligation of professional secrecy and keep all your data confidential.

**Withdrawal of consent**

Your decision of giving consent, to the usage and processing of your data and/or images for this case report, is completely voluntary. If you refuse, no further actions need to be done. You don’t have to sign anything or justify your decision. Also, you can always withdraw your consent, without any reason. Your decision won’t affect the quality of your further medical care in any manner.

However, once this case report is published and/or presented, it is no longer possible to withdraw your consent.

**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 or e-mail: **[Provide all contact details]**

If you have any questions relating to your rights as a patient in a case report, you can contact the patient rights ombudsman of your institution on this telephone number: +32 16 34 48 18. If necessary, he/she can put you in contact with the ethics committee.

Title of the case report: Official title in English and simplified version understandable for non-experts

**II Informed consent**

**Patient**

I declare that I have been informed of the nature of this case report and its purpose.

I have taken note of the information document.

I have had sufficient time to think this through and discuss it with a person of my choice (general practitioner, relative).

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

I understand that my consent is voluntarily and that I can withdraw my consent at any time, without justifying my decision. I am aware that this decision won’t harm me in any possible manner. I am informed about the fact that I cannot withdraw my consent once this case report has been published and/or presented.

I understand that for this case report, previously collected data and/or images will be used and processed. Confidentiality of these data and images is guaranteed by the investigator, in accordance with applicable European and Belgian legislation.

**[Depends from the study, delete if irrelevant]** I agree / I don’t agree (delete as appropriate) that my general practitioner or other specialists who take care of my health can be contacted to obtain additional information about my health, if necessary.

1. **[If applicable]** As indicated in Chapter I, The investigator (the physician) would like to use your data (i.e. medical data and/or images) in a pseudonymized format for (medical) scientific publications, presentations on scientific congresses. Do you agree that your (medical) images and/or data will be used for (medical) scientific publications and / or presentations on scientific congresses?

 **(Tick as appropriate; If you don’t fill in this question, we assume your answer is “I don’t agree”)**

|  |  |
| --- | --- |
| **☐ I agree** | **☐ I don’t agree** |

I received a copy of the information and the informed consent.

Name, surname, date and patient’s signature.

**[If the patient is incapable]** **Legal representative**

I declare that I have been informed of the request to make a decision about the processing and use of relevant images and/or (medical) data in a case report of the person I am representing in his or 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.

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

Surname, first name and relationship to the person represented:

Date and signature of the legal representative.

**[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 case report was adequately provided, and that the patient (or his/her legal representative) probably understood the information. I confirm that consent to participate in the case report was given voluntarily.

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 case report and have given the patient 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”.

Surname, first name, date and signature Surname, first name, date and signature

 of the investigator’s representative of the investigator

Title of the case report: Official title in English and simplified version understandable for non-experts

### III Supplementary information

**1: Supplementary information on the protection and rights of the patient**

### *Ethics Committee*

This study has been reviewed by an independent Ethics Committee, namely the Ethics Committee Research UZ/KU Leuven, which has issued a favorable opinion. 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 patient in a clinical study are respected, that based on current knowledge, the study is scientifically relevant and ethical.
This favorable opinion of the Ethics Committee should never been interpreted as an incentive to take part in this case report.

### *Voluntary participation*

Before signing, do not hesitate to ask any questions. Take the time to discuss your participation with a confidant (like a family member or friend).

You do not have to consent with the processing and usage of your data and/or images for a case report. You also have the right to withdraw your earlier given consent, without justifying your decision. Your decision won’t have any negative consequences. Once the case report is published and/or presented, consent can’t be withdrawn anymore.

If you agree to take part in this case report, 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 case report. You will receive a copy of the form.

**Costs associated with your participation**

You will not receive any compensation for your participation in this case report. Furthermore, the case report will not involve any additional costs for you.

***Guarantee of confidentiality***

Your participation in the study means that the investigator (physician) will draft and publish a case report based on earlier collected (medical) data and/or images.

Your data will be processed in accordance with the European General Data Protection Regulation (GDPR). UZ Leuven shall act as data controller for your data.

You are entitled to ask the investigator which personal data will be collected and how it will be used in this case report. You have the right to review these data and make corrections if necessary.

The physician and his/her team will be perpetually subject to the obligation of professional secrecy and keep all your data confidential. This means that he/she commits to protect your identity at all times and will never reveal your name in the context of a publication or conference. In this regard, he/she will pseudonimize your data and/or images (your identity will be encoded and identifiable elements on medical images will be deleted if possible) before publication and/or presentation. For example, your name and date of birth will be deleted before publication/ presentation.

 **[If applicable]** In case there are images used in this case report, these will be modified and de-identified to protect your privacy. **[Specify how these images will be processed, for example: Your eyes and mouth will be permanently masked by digitally inserting a “black box” to cover these zones. Other identifiable characteristics like tattoos, birthmarks or other identifiable elements on your body will be covered too. – Specify for this case report.]**

It is possible that these (encoded) data will be shared with Belgian or other regulatory authorities, the ethics committees, other doctors and/or to organizations working in collaboration with UZ Leuven.

**[delete if no medical records will be used]**

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

UZ Leuven confirms that these data and/or images will only be used for this case report.

Case reports from **UZ Leuven:** If you have any questions regarding the processing of your data, 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.

Finally, if you have a complaint concerning the processing of your data, you can contact the Belgian supervisory authority who supervises whether all basic grounds for privacy protection are complied.

The Belgian supervisory authority is called:

Gegevensbeschermingsautoriteit (GBA)

Drukpersstraat 35,

1000 Brussel

Tel. +32 2 274 48 00

e-mail: contact(at)apd-gba.be

Website: [www.gegevensbeschermingsautoriteit.be](http://www.gegevensbeschermingsautoriteit.be)

**Duplicate for the researcher**

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