* All the indications in red shall be deleted in the final version, and the italic font shall be replaced by a regular upright style.
* With the exception of certain dissertations (physiotherapy, podiatry, nutrition, etc.), this document should only be used for non-interventional or interventional studies, but consisting solely of questionnaires. For interventional studies, the national models of the FAMHP are more suitable.
* If the study concerns **minors** (less than 18 years old):
  + Provide an information document and an assent form for them, adapted to their age (see Procedure for drafting an information document for participants in biomedical research, AAHRPP-SOP-051[[1]](#footnote-1)).
  + Adapt the text below as to address the document to the TWO parents: "information for the parents", "Your child is invited to participate", "Parents' informed consent form", "We, the undersigned, ...", "Surname, First name, Date and Signature of parent 1", "Surname, First name, Date and Signature of parent 2", ...)

# INFORMATION for the *PATIENT/PARTICIPANT* (choose)

|  |
| --- |
| Insert the title of the protocol in French |

You are invited to participate voluntarily in an *experiment / survey* (if questionnaires: choose survey; otherwise, choose experiment - ditto throughout the rest of the document). Before agreeing to participate, it is important to read this form which describes its purpose and practical details. You have the right to ask questions at any time in connection with this *experiment / survey*.

**Objective and description of the *experiment / survey***

This is an *experiment / survey* which should include approximately (number) *patients / participants* ~~(choose - same throughout the rest of the document), approximately (number)~~ in Belgium.

The objective of this *experiment / survey* is to ...

If you agree to participate in this experiment / survey, you will be asked to (practical methods: questionnaire, etc.) …

You will be asked to participate in the *experiment / survey* for approximately (months / weeks, until a certain event, ...)

**Sponsor of the of the experiment / survey**

The sponsor of the *experiment / survey* is ... (within the meaning of the law of May 7, 2004, that is to say the university, the hospital, ... - it is NOT the supervisor of the dissertation)

**Voluntary participation**

Your participation in this *experiment / survey* is entirely voluntary and you have the right to refuse to participate. You also have the right to withdraw from the *experiment / survey* at any time, without specifying the reason, even after having signed the consent form. You will not have to provide a reason for withdrawing your consent to participate; however, the data collected until ceasing the participation in *experiment / survey* will be an integral part thereof. Your refusal to participate in this *experiment / survey* will not result in any penalty or loss of benefits for you.

(Add, if applicable, but in the case of a survey this is not needed:)

Your medical treatment will not be affected by your decision. Your attending physician will be notified of your participation in *the experiment / survey* if you wish.

**Risks and benefits**

We cannot assure you that if you agree to participate in *this experiment / survey*, you will personally have a direct benefit from your participation.

(Add if applicable :)

However, the information obtained through this study can contribute to a better understanding of… in…

(For non-interventional studies, add if needed :)

There is no risk of participation in this experiment / survey except for a possible breach of confidentiality of the data.

**No-fault Insurance**

If you or your successors (family) suffer damage related to this *experiment / survey*, this damage will be compensated by the sponsor of the study in accordance with the law relating to experiments (do not change the term) in human beings of May 7, 2004. You don't have to prove anyone's fault.

Insurer's names and contact details:

………………………………………………………………………………………………………………………

Insurance Policy number:

………………………………………………………………………………………………………………………

**Protection of privacy**

Your identity and your participation in this *experiment / survey* will remain strictly confidential. Explain how the data will be kept confidential. If it is via a code, explain how the data will be coded). You will not be identified by name or in any other recognizable manner in any of the study files, results or publications. (You must specify the name of the person who is the data manager and mention how long the data will be kept.)

The protection of personal data is ensured by the law of July 30, 2018 relating to the protection of privacy and by European and Belgian regulations (general European regulations on the protection of personal data (RGPD) of May 25, 2018) in force. These rights are also guaranteed by the law of August 22, 2002 relating to the patient rights. *(This latest law has to be mentioned only if there are patients planned in the study. Not in case of healthy volunteers.)*

According to the GDPR, you have the right to know how your data are treated. If you have any questions on this subject, you can contact the data protection officer of the study centrer at the following address: (If the study takes place at Cliniques Universitaires Saint-Luc, indicate: rgpd@saintluc.uclouvain.be - If the study takes place at UCLouvain, indicate: privacy@uclouvain.be).

In the event of a complaint regarding the treatment of your data, you can contact the Belgian Data Protection Authority: Rue de la Presse 35 - 1000 Bruxelles - Tél. : 02 274 48 00 - e-mail: contact@apd-gba.be

**Ethics Committee**

This *experiment / survey* is evaluated by an independent ethics committee, namely the committee… (mention the name of the ethics committee that issued the single opinion and if applicable the name of the local ethics committees - note: the ethics committee of Saint-Luc - UCLouvain is called Comité d’Ethique Hospitalo-Facultaire Saint-Luc - UCLouvain), who issued a favourable opinion on ……………………. (do not complete at this stage, but at the start of the study, mention the date which appears on the final agreement of the ethics committee).

**Persons to contact if you have questions about the *experiment / survey***

f you feel that you have suffered damage related to *experiment / survey* or if you have questions, want to give an opinion or express concerns about the experiment or about your rights as a patient participating in a clinical study, now , during or after your participation, you can contact :

Responsible for the study: ……………………………………………………………………………………………………………………

Email : …………………………………………….. (e-mail l’address Uclouvain or St-Luc, not a private address like gmail, hotmail…, for privacy reasons.)

Phone: ……………………………………… (preferably a belgian phone number, if possible).

(If the study takes place at the Cliniques universitaires Saint Luc, mention in addition :)

For the management of complaints not resolved by the investigator, you can contact the hospital's ombudsman for patient rights:

E-mail: mediateur@saintluc.uclouvain.be

~~Phone : 02 764 16 05~~

(If the study takes place at UCLouvain or elsewhere, please mention :)

For the management of complaints not resolved by the investigator, you can contact the Ethics Committee:

E-mail : commission.ethique-saintluc@uclouvain.be

~~Phone : 02 764 55 14~~

***PATIENT/PARTICIPANT* INFORMED CONSENT FORM**

1. I, the undersigned (SURNAME, First name(s)), ………………………………………………………………………………

declare having read the above information and agree to participate in (title of survey or experiment)

…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

For the consent of the parents of a minor participant, provide the Names, First names and signatures of BOTH parents exercising legal authority over the minor or, alternatively, the Surname, First names and signature of the minor's tutor.

1. I was given a copy of this signed and dated informed consent form, as well as the *patient / participant* information note. I have received an explanation regarding the nature, purpose, duration of the *experiment / survey* and I have been informed of what is expected of me. I was given the time and the opportunity to ask questions about *experiment / survey*; I received a satisfactory answer to all my questions. (Add, if applicable ::) the *intervention/ treatment* (choose) was explained to me in detail, including the side effects and potential known risks.
2. I was informed that an insurance policy was taken out.
3. I know that this *experiment / survey* as been submitted and approved by Comité d’Ethique Hospitalo-Facultaire Saint-Luc - UCLouvain.
4. I am free to decide whether to participate or not, whether to stop the *experiment / survey* at any time without the need to justify my decision and without this causing any disadvantage.
5. By signing this document, I authorize the use of my personal data in compliance with
   * ~~The Belgian law of 30 July 2018 on the protection of privacy ;~~
   * The Law of 22 August 2002 on patient rights ; *(to be mentioned only if there are patients planned in the study)*
   * The Law of 7 May 2004 relating to experimentation in the human beings ;
   * European and Belgian regulations (general European regulations on the protection of personal data (RGPD) of May 25, 2018 and the Belgian law of 30 July 2018 on the protection of privacy) in force.
6. I have not suffered any undue physical or psychological pressure for my participation in the *experiment / survey*.
7. I voluntarily consent to participate in this *experiment / survey.*

…………………………………………………………………… …...…/…..…./20…..…

Surname, First name, Signature Date (day/month/year)

Of the *patient /participant*

I, the undersigned, Mrs / Miss / Mr. (SURNAME, First name(s)) ………………………………………… confirm that I have explained the nature, purpose and duration of the *experiment / survey* to the *patient / participant* mentioned ) above..

…………………………………………………………………… …...…/…..…./20…..…

Signature of the person providing the information Date (day/month/year)

1. AAHRPP-SOP-051\_Rédaction - ICF - Procédure de rédaction d'un document d'information du participant à une recherche biomédicale [↑](#footnote-ref-1)