
	<b>Academic Studies - Checklist</b> <b>important information to be found</b> <b>in the ICF</b>	
		<b>Commission d'éthique</b> <b>hospitalo-facultaire</b>
CEHF-DSQ-119-2.0		Date d'application : 08/11/2023

## 1. General notes:

### 1.1 ICF<sup>1</sup> FORMAT :

*information document and consent form limited to fifteen pages:*

#### 1. Essential information in deciding on participation :

This part shall contain all the information essential to the participant's decision-making process such as:

- a. a presentation of the participant's rights (voluntary participation; right to withdrawal)
- b. a clear description of the research project (context, objectives, inclusion / exclusion criteria, methodology & development) with highlights of additional constraints to standard treatment (not study related), useful information such as the number, frequency and content of each of the visits as foreseen in the study, as well as the alternative treatments
- c. a descriptions of the risks & benefits and a presentation of measures taken to minimize the risks, more detailed information concerning the rights of participants; confidentiality; insurance

➔ The ICF model for dissertations and TFE<sup>2</sup> on the CEHF<sup>3</sup>/CTC<sup>4</sup> website can be used for the structuring the chapters only (it can serve as a basis), but it is incomplete in terms of its content.

#### 2. The page with the consent form;

### 1.2 EDITORIAL QUALITIES:

*The ICF should be written in such a way that it can be read and understood by people who are not healthcare professionals, who have not received the oral information and which the potential participant may wish to consult.*

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

- a. Structured information, clear thread;
- b. Correct phrasing (watch out for problems with literal translation from English to French / Dutch, inappropriate choice of terms, etc.);
- c. Short sentences, language understandable by the majority of participants for whom the document is intended;
- d. Absence of professional jargon;
- e. For the same concept, keep the same terminology throughout the document (example: do not talk about study then research and then clinical trial);
- f. Avoid too many abbreviations;
- g. Avoid spelling errors ;
- h. Sufficient font size (Reference: ≥ Arial 10) especially when the likely ICF reader is likely to have vision problems.

<sup>1</sup> ICF : informed consent form

<sup>2</sup> TFE : travaux de fin d'études / graduate thesis

<sup>3</sup> CEHF : ethics comite / Comité d'éthique hospitalo-facultaire CUSL-UCLouvain

<sup>4</sup> CTC : Clinical trial center

### 1.3 ADMINISTRATIVE REQUIREMENTS

1. The 3 parts of the document, namely the information to the participant / legal representative, the consent and the additional information (appendices) form a single document and are therefore identified by the same version number and the same date of publication
2. Each part will include the full title of the study in the drafting.
3. The pagination of the whole document will be presented in " X / Y pages" format

## 2. Who to contact should you have questions?

It is good practice to provide the following table on page 2. This table comes from the New National FAMHP<sup>5</sup> Template dated June 2019

Name	Function	In case of	Contact details
Surname, first name	principal Investigator of the study centre	Information, problems or concerns	E-mail, Telephone N°
	Study personel	Information, problems, concerns, questions about your rights as a participant in a study	E-mail, Telephone N°
	Emergency contact [! not the hospital emergency department!]	Emergency	E-mail, Telephone N°
	Patient Rights Ombudsman	Concerns about your rights as a study participant	E-mail, Telephone N°
Name and address of the sponsor's insurance company & contact details of the insurer	Sponsor's insurance company	In the event of a disagreement or complaint concerning a claim	Insurance Policy n° E-mail, Telephone N°
	Data protection officer(DPO) of the study centre	Questions relating to the confidentiality of your data	E-mail, Telephone N°
	Belgian data protection authority	Complaints about the confidentiality of your data	E-mail : <a href="mailto:contact@apd-gba.be">contact@apd-gba.be</a>

### 3. Non-exhaustive checklist of important information to find in the ICF:

- In the section "objectives and conduct of the study": Specify the purpose of the study
- Specify
  - o the number of participants
  - o what will be asked of the participant and how long it will take
  - o how participants will be recruited. If recruitment material is used (posters, website) they must be submitted to the Ethics Committee for opinion
  - o how will participants will be randomized
  - o If possible, specify the duties of the participant
- Mention that participation is voluntary
- Mention that the participant can withdraw from the study at any time
- Specify that one or more Ethics Committees has / have issued an opinion (mono- / multi-centric study)
- In the « **Benefits and Risks** » section: Mention that the study will not necessarily give a benefit to the participant, but that it could allow a better understanding of the pathology. Also specify the risks.
 

In the case of an observational study (prospective non-interventional), note that there is always a possible risk of breach of confidentiality (this is why insurance shall be taken out) as follows: « *In an observational study, the only risk possible would be a flaw in the measures taken to protect the confidentiality of your personal data.* »
- In the « **confidentiality guarantees** » section, mention the Belgian laws + GDPR <sup>6</sup> :
 

« *These rights are guaranteed to you by the general European data protection regulations of 27 April 2016 (in force since 25 May 2018) and by the Belgian law of 30 July 2018 relating to the protection of privacy with regard to processing of personal data and by the Belgian law of 22 August 2002 relating to the rights of the patient.* »

**FR** : « *Ces droits vous sont garantis par la réglementation générale européenne sur la protection des données du 27 avril 2016 (en application depuis le 25 mai 2018) et par la loi belge du 30 juillet 2018 relative à la protection de la vie privée à l'égard des traitements de données à caractère personnel et par la loi belge du 22 août 2002 relative aux droits du patient.* »

**NL** : « *Deze rechten zijn bepaald door de Europese Algemene Verordening Gegevensbescherming van 27 april 2016 (sinds 25 mei 2018 van kracht) en door de Belgische wet van 30 juli 2018 tot bescherming van de persoonlijke levenssfeer ten opzichte van de verwerking van persoonsgegevens en door de Belgische wet van 22 augustus 2002 betreffende de rechten van de patiënt.* »
- In the « **confidentiality guarantees** » section, mention the coordinates of the local DP : you may refer to the table on page 2.

**CUSL** : «*You can contact the data protection officer of the study centre at: [rapd@saintluc.uclouvain.be](mailto:rapd@saintluc.uclouvain.be).* »

**UCL** : «*You can contact the data protection officer of the study centre at: [privacy@uclouvain.be](mailto:privacy@uclouvain.be).* »

- In the « [confidentiality guarantees](#) » section, mention the possible APD<sup>7</sup> contact:
 

« You also have the right to lodge a complaint concerning the mode of treatment of your data with the Belgian controlling authority responsible for ensuring compliance with the data protection legislation: Data Protection Authority (APD) - Rue de la Presse 35 - 1000 Bruxelles - e-mail : [contact@apd-gba.be](mailto:contact@apd-gba.be) »

**FR** : « Vous avez également le droit d'introduire une plainte concernant le mode de traitement de vos données auprès de l'autorité Belge de contrôle chargée de veiller au respect de la législation sur la protection des données : Autorité de protection des données (APD) - Rue de la Presse 35 - 1000 Bruxelles - e-mail : [contact@apd-gba.be](mailto:contact@apd-gba.be) »

**NL** : « U hebt het recht om een klacht in te dienen over hoe uw informatie wordt behandeld, bij de Belgische toezichthoudende instantie die verantwoordelijk is voor het handhaven van de wetgeving inzake gegevensbescherming : Gegevensbeschermingsautoriteit (GBA) – Drukpersstraat 35, 1000 Brussel - e-mail : [contact@apd-gba.be](mailto:contact@apd-gba.be) ».
- Section « [Contact](#) » : Mention the contact details of the principal investigator and the ombudsman : you may refer to the table on page 2.

**CUSL** : «For the management of complaints not resolved by the investigator, you may contact the ombudsman of the Cliniques Universitaires Saint-Luc at the following address: [mediateur@saintluc.uclouvain.be](mailto:mediateur@saintluc.uclouvain.be) . »

**UCL** : There is no specific mediator for UCLouvain. Mention the name of an independent contact person on the team. If no one can be found, you can mention the ethics committee as a last resort:

«For the management of complaints not resolved by the investigator, you can contact the ethics committee hospitalo facultaire Saint-Luc UCLouvain. E-mail : [commission.ethique-saintluc@uclouvain.be](mailto:commission.ethique-saintluc@uclouvain.be) . »
- Section « [insurance](#) » : Mention the full contact details of the insurance (name of the insurance company, policy number, contact details) : you may refer to the table on page 2. - Also mention the following sentence:
 

« Any participation in a clinical study involves a risk as small as it is. The sponsor assumes, even in the absence of fault, the damage caused to the participant (or in the event of death, to his beneficiaries) and linked directly or indirectly to his participation in the study. The sponsor has taken out an insurance contract for this liability, in accordance with article 29 of the Belgian law relating to experiments on human beings (May 7, 2004). »

**FR** : « Toute participation à une étude clinique comprend un risque aussi petit soit-il. Le promoteur assume, même en l'absence de faute, la responsabilité du dommage causé au participant (ou en cas de décès, à ses ayants-droit) et lié de manière directe ou indirecte à sa participation à la recherche. Le promoteur a souscrit un contrat d'assurance de cette responsabilité, conformément à l'article 29 de la loi belge relative aux expérimentations sur la personne humaine (7 mai 2004). »

**NL** : « Elke deelname aan een studie houdt een risico in, hoe klein ook. De opdrachtgever is - ook indien er geen sprake is van fout - aansprakelijk voor de schade die de deelnemer of in geval van overlijden zijn/haar rechthebbenden, oplopen en die rechtstreeks of onrechtstreeks verband houdt met diens deelname aan de studie. U moet hiervoor dus geen fout aantonen. De opdrachtgever heeft voor deze aansprakelijkheid een verzekering afgesloten, in overeenstemming met artikel 29 van de Belgische Wet betreffende experimenten op de menselijke persoon (7 mei 2004).»
- If applicable, mention the name and address of the [sample bank](#) (place where the samples are stored) and specify when the samples will be destroyed..

<sup>7</sup> APD : Autorité de protection des données / GBA : Gegevensbeschermingsautoriteit / data protection authority

- If there is a possibility of [incidental discoveries](#), mention it and specify how the patient will be informed
- Specify the [guarantees of confidentiality](#) (pseudonymisation (coded data) or anonymization of data). Specify how the code will be composed. As a reminder, the database containing the study results cannot contain any combination of elements such as initials, sex and complete date of birth (dd/mm/yyyy).
- Mention the [Surname + First names](#) in the signature section of the consent page
- If [minors](#) will be recruited, provide [information and assent documents](#) in a language adapted to each age group: 6-11 years, 12-15 years and 16-17 years, to be signed by the children. Also provide information documents and consent to be signed by both parents / guardians.