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Circular n° 604
To the presidents of the ethics committees and
the sponsors of clinical trials

Your letter from Your reference Our reference Annex Date

THIS DOCUMENT IS A TRANSLATION OF THE OFFICIAL AND SIGNED VERSIONS IN DUTCH AND FRENCH.

Templates for informed consent

Sir, Madam

In November 2011, several Belgian Ethics Committees took the initiative to develop templates for informed consent. Several reasons lead to the start of this project:

- the excessive increase of the number of pages of informed consent documents,
- different templates between companies,
- lack of structure,
- repetitions and irrelevant information, etc.

As a result, the informed consent document often is a very complicated document, difficult to be understood unassisted by lay people. Hence, it is doubtful trial subjects and even members of the research staff will review the document in its entirety during the process of obtaining consent.

The Declaration of Helsinki, the Guideline for Good Clinical Practice and the Belgian law on experiments focus on the obligation of informed consent and the level of information to provide to the person who will accept to participate in an experiment and who will accept the processing of his/her personal data and / or his/her samples of human body material for research purposes.

The creation of and the use by all of a proper template for informed consent, validated by the Ethics Committees, should lead to the following advantages:

- a simplification of editorial work,
- a simplification of evaluation work by the Ethics Committee,
- harmonization of the requirements towards the sponsors,
- a simplification in the process of informing the patient
- and better information to the patient.

These templates were developed with specific attention to the following aspects:

- structured information, clear guiding principle;
- understandable language: correct sentence structure, short sentences, absence of technical language, use of the identical terminology throughout the entire document, avoid use of too much abbreviations, free of spelling errors;
- sufficient font size policy (minimum = Arial 10);
- sufficient interspaces throughout text.

The need for structured information is achieved by dividing the document into 3 parts, all 3 receiving page numbering:

1. Information vital to the decision to take part: essential information for understanding of the research.
This section is limited to a maximum of 5 pages. The first page should be an introduction, defining the concept of a clinical study and listing the rights of the participant. The following 4 pages should mention the objectives and a description of the study protocol, the course of the study, risks and discomforts, notification of new information (where applicable), benefits, alternative treatment(s), withdrawal from the study, treatment after stopping the study, treatment of samples of body material collected during the study (if applicable), obligations for and advices to participants, contact persons. An optional front page can be added as well, mentioning only the study title, sponsor identification, Belgian or European representative of the sponsor, local investigators, local contacts and table of contents.
2. Informed consent: the consent itself.
This section contains the consent form of the participant, wording of the role of the legal representative, and of the witness or the interpreter, wording of the ethics commitment of the principle investigator and his or her research team. The consent form is a contract between the participant and the investigator.
3. Supplementary information: information which is not immediately part of the decision process.
Annex 1: supplementary information on the organisation of the study
Annex 2: supplementary information on the risks associated with participation in the study
Annex 3: supplementary information on the protection and the rights of the participant in a clinical study

The sequence of these parts can be adapted.

The first part should always be the vital information.

The following two parts can be switched.

The informed consent document should be as short as possible and, apart of the optional front page, cannot be more than 15 pages long.

In total, 4 different templates have been developed:

1. A basic model for interventional clinical trials on adults capable of autonomy,
2. A specific introduction for the inclusion of a participant with consent of a legal representative,
3. A specific introduction for the inclusion of a participant in an emergency situation,
4. A basic model for non-interventional studies on adults.

These templates have been agreed and approved during the Clinical Trial Taskforce meeting of June 26, 2013. The FAMHP strongly supports the use of these templates. All four templates can be downloaded at the FAMHP website under section "Human medicines", "Research & Development", "Ethic Committee", "Templates for informed consent". With some adjustments they can be used for clinical studies on medical devices as well.

Since these templates for informed consent have been published in August 2013, they will be re-evaluated in September 2014 in the presence of all Ethics Committees with a complete recognition. The term of the subsequent evaluation periods can be longer, for example 2 to 3 years. Comments or suggestions can be sent to ct.rd@fagg.be with the subject "informed consent templates".

Thank you for noting the contents of this circular.