

INFORMATION FOR ETHICS COMMITTEES AND SPONSORS ON THE INFORMED CONSENT PROCEDURE IN TRIALS ONGOING AT OR COMPLETED BEFORE 25TH MAY 2018.

From May 25 2018 onwards the EU General Data Protection Regulation (GDPR)¹ is effective. This also implies additional requirements on the collection and use of personal data in clinical trials. The Belgian Association of Research Ethics Committees (BAREC), and the Clinical Trial College (CT-College) received a lot of questions from sponsors and ethics committees on the implementation of the GDPR in the Informed Consent procedure of ongoing and completed clinical trials. Please find below some frequently asked questions and the recommendations which were adopted at the meeting of 28/08/2018 and 04/12/2018 of the Workgroup on Informed Consent Form.

Please note that in this document the patient rights are in accordance with the law published on 30/7/2018².

This document will be published on the website of the [CT-College](#).

Who is responsible for the GDPR compliancy check of the trial dossier?

The responsibility for the GDPR compliancy check of the clinical trial dossier lies with the data controller of the trial, *i.e.* the sponsor (and its data protection officer) or in case of joint controlling, the sponsor and the investigator. The ethics committee that evaluates a substantial modification for an ongoing trial, in particular if this includes modifications of the informed consent form, has to verify the compliance of these documents with the new regulation. However the ethics committee is not obliged to proactively write the data controller(s) of ongoing trials to take action with regard to GDPR.

Will the templates for Informed Consent Form (ICF) available on the website of the FAMHP be adapted with the new regulation on personal data processing?

Yes, the templates for ICF are being revised by a Workgroup consisting of representatives of ethics committees, Barec, pharma.be and patient organizations. As soon as available, the revised templates will be published on the website of the [CT-College](#).

Does supplementary information needs to be provided to participants of ongoing or completed trials?

- No further information needs to be provided to participants for which data collection has been completed before 25th May 2018.
- Supplementary information needs to be provided to participants that have been included in ongoing trials before or after 25th May 2018 and for which new personal data will be collected after 25th May 2018.

If applicable, and if not yet included in the signed ICF, which supplementary information needs to be provided to participants?

If not yet available in the signed ICF, the following information needs to be provided:

- the full reference to the General Data Protection Regulation No 2016/679.
- a clear definition of “your personal data” as “name, initials, address, information on your health and medical condition including your medical history but also some of your background (e.g. your age, sex, and ethnic origin) and the results of examinations required by the trial”.
- the right to request information on and a copy of “your personal data”
- the right to request a correction of “your personal data”
- if applicable, the right to request deletion of “your personal data”
- name and contact details of the data processor, *i.e.* the investigator
- the legal base for data processing
- name of the data controller
- name and contact details of the data protection officer of the site where the trial is conducted
- name and contact details of the Belgian Data Protection Authority
- the right to file a complaint about the processing of your personal data to the Belgian Data Protection Authority
- a list of persons subject to professional secrecy, that are allowed to examine information in “your medical records relevant for the trial”, this to enable them to verify the quality of the trial, including that if the person resides in a non-EU country where the standards in terms of the protection of personal data are different or less stringent, the sponsor will respect the constraints of the European regulation and the Belgian legislation on the protection of privacy, and will ensure equivalent guaranties for the transfer of the trial data.
- the (legal) retention period of “your personal data” and possible archiving purposes
- the intention of further processing of “your personal data” and the purpose for this secondary processing

If applicable, how should supplementary information be provided to participants of trials?

The supplementary information described above should be provided to participants via:

- an information leaflet which is not signed by the participant, or
- an information leaflet which is signed by the participant for acknowledgement, or
- an adapted ICF, in which is clearly indicated which parts of the document have changed, and which should be signed by the participant.

An example of an information leaflet is provided in the [annex \(nl, fr, en\)](#) to this document³.

In most trials ongoing at May 25th 2018, the legal base for data collection and processing is “consent”. If there is an essential change in the rights of the participant on the collection and processing of his personal data, e.g. a new legal base is defined, it is mandatory that the leaflet is signed.

If applicable, when should supplementary information be provided to the evaluating EC?

The supplementary information needs to be provided to the evaluating EC as a substantial modification at the latest at the occasion of

- the next substantial modification or
- the next progress report (to be provided within 1 year after the trial start and each year thereafter as long as the trial is active),

whichever comes first.

After approval by the EC, the supplementary information is provided to the participant.

Document Revision History

Version No. (Date of publication)	Revision description
2.0 (05/12/2018)	-Introduction: Addition of reference to the law of 30/7/2018 on data protection. -FAQ on “which information”: Addition of reference to the GDPR. -FAQ on “how”: Clarification on when a signature of the participant is needed for the information leaflet. -FAQ on “when”: The documents must be submitted via a substantial modification to the evaluating EC.

The recommendations above were discussed during the meetings of the Workgroup Informed Consent Form of 27/11/2018 and 04/12/2018 (version 2.0). Information leaflets that have been sent to the participants prior to the publication of this advice document should not be adapted.

Participants present at these meetings:

Version 2.0: A. Lintermans (Vlaams Patiëntenplatform), E. Claes & L. Seghers (EC UZ Leuven), B. De Brabant represented by D. Lossignol (EC Institut Jules Bordet), B. Vanderhaegen represented by C. Vansteenkiste (Barec), A. Van Scharen (VUB & EC UZ Brussel), N. Lambot (pharma.be), P. Terneven (Sanofi), G. Di Matteo (Pfizer), S. Vanhiesbecq, L. Marynen & K. Anciaux (FPS Health, Food Chain Safety and Environment, CT-College)

REFERENCES

¹ General Data Protection Regulation No 2016/679 of the European Parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

² Wet betreffende de bescherming van natuurlijke personen met betrekking tot de verwerking van persoonsgegevens. Loi relative à la protection des personnes physiques à l'égard des traitements de données à caractère personnel. Applicable since 5/9/2018

³ The template provided in annex is a modified version of the template letter that is proposed by the EC Onderzoek UZ KULeuven to the Sponsor to use in case they prefer to inform the patients about the GDPR.