Newsletter
Ethics Committee Research UZ/KU Leuven
Number 8 – December 2019

Dear researchers and teams

With this newsletter we would like to share some tips and tricks enabling and supporting high-quality clinical research with respect for the well-being and privacy of each patient and volunteer.

We wish you all a Merry Christmas and a happy 2020!

Ethics Committee Research UZ/KU Leuven

Members: Ariel Alonso Abad, Dominique Bullens, Simon Brumagne, Pascal Borry, Xavier Bossuyt, Lut De Groote, Jan de Hoon, Hélène De Somer, Jean-Jacques Derèze, Lieve Goossens, Stefanie Goris, André Loeckx, Kristof Muylaert, Ben Nemery, Marleen Renard, Katrin Roggeman, Miet Schetz, Karin Sipido, Anne Smits, Mathijs Swaak, Josse Thomas, José Thomas, Anne Uyttebroeck, Ben Van Calster, Veerle Vanparys, Jan Verhaegen, Gregor Verhoef, Minne Casteels

Staff: Valerie Alderweireldt, Eveline Claes, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Greet Verbeeck, Sofie Vervoort

1. Protocol synopsis

According to the law of 7 May 2017, the protocol synopsis should be submitted in the 3 national languages (FR, NL, DE). As the protocol synopsis can be used for evaluation by the layperson (patient representative) of Ethics Committee (EC) Research UZ/KU Leuven, we ask you to submit at least a protocol synopsis in Dutch when EC Research acts as the central ethics committee in the study.

2. New website in January 2020

The layout of the UZ Leuven website will be renewed in January 2020, and hence, the website of EC Research as well. Both layout and structure will be updated. It will be easier to identify *which studies* have to be submitted to EC and *how* they have to be submitted. We recommend to check our Frequently Asked Questions (FAQ). In short, it is worth to take a look at it!

3. GDPR Questionnaire

As mentioned in our previous newsletter, in order to facilitate the contract review by the legal department (if applicable) and to allow a privacy check by the ethics committee you will be requested (see message in the email of CTC in which the assigned S-number is mentioned) to complete the GDPR questionnaire.
The GDPR questionnaire needs to be completed for each study or research project for which UZ/KU Leuven acts either as sponsor or as participating site and in which personal data are processed.
A copy of the duly completed GDPR questionnaire is a necessary part of a submission to EC Research. This implies that the copy should be included in the submission package sent to the EC research.
The GDPR questionnaire and the guidance document for completing such questionnaire can be found on the CTC's website: http://wiki/display/ctc/GDPR.

EC would like to highlight the following points:

- Data are considered **anonymous** only when the information does not relate to an identified or identifiable person. "Anonymous" is perceived by GDPR as a very restrictive concept. Because data are considered anonymous only when nor you or nor anyone else can (re-)identify the individuals whom the data concern, the qualification of "anonymous" will in the context of healthcare and research for which health related data are processed, only apply to very limited cases (such as potentially in case of aggregated data).

- Data concerning health are considered to be **special** (or sensitive) categories of personal data. "Data concerning health" means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.

- **Lawful basis**: in case UZ Leuven is sponsor and your research project or study is considered as 'academic' , you are advised to build on 'public interest' as the lawful basis for your study or project. Academic research is carried out to contribute to an increase of knowledge and insight that will benefit (directly or indirectly) society and research is one of the essential tasks of a university hospital. Please be aware that although informed consent can also be used as a lawful basis, it is not necessarily the preferred option as it may have several disadvantages for the researcher and the legality of informed consent in a researcher–participant relationship may be questioned. If UZ Leuven is not the sponsor, you must rely on the advice of the sponsor to determine the lawful basis and complete the GDPR questionnaire.

- The section "**Research**" in the GDPR questionnaire (title/description/purpose(s)) needs to be completed in Dutch as it will serve to properly inform the subjects in accordance with the information and transparency obligation under GDPR. The information to be included herein should therefore be:
    - brief (not too long);
    - complete;
    - and described in an understandable language.

In summary, it should inform the patient, but not lead to additional questions from the patient.

4. Quality of academic studies

In the previous newsletter of EC, a topic about the (often inadequate) quality of academic studies was included. EC would like to direct you to the following website of the "Leuven Biostatistics and statistical Bioinformatics Centre (L-BioStat)": https://gbiomed.kuleuven.be/english/research/50000687/50000696.

To all researchers of the Group Biomedical Sciences, L-BioStat offers consultation to provide statistical advice on various methodological and statistical aspects of the research project. Free advice is provided through scheduled one hour consulting appointments. Further, it also offers in-depth collaborative consulting, including analysis of data, writing of a statistical report and incorporation of the results in (an) article(s).

You can also discuss/collaborate with colleagues from several departments in KU Leuven with extensive biostatistical expertise, both in Biomedical Sciences as in the other groups.

5. FDA 1572 form

The FDA 1572 form is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational medicinal product. By signing this FDA 1572 form, the investigator is informed of his/her obligations and commits to follow pertinent FDA regulations.

Sponsors often want to obtain a completed and signed 1572 form by the investigator before permitting the investigator to participate in the clinical trial. Investigators are, however, often unaware of the requirements for themselves and for the ethics committees listed in these forms.Sometimes these requirements cannot be met (e.g. role and composition of an IRB).

In addition, this document is not an absolute requirement for the FDA as there are several options available to use the data and to comply with FDA regulation without this form. For example, 21CFR §312.120 "Foreign clinical studies not conducted under an IND" states that the data will be accepted if the design and conduct of the clinical trial is **GCP compliant** and their inspectors can inspect on-site if desired.

If the study is carried out in accordance with ethics and data quality standards as described in national legislation and EU Directives 2001/20/EC, 2001/83/EC, and 2005/28/EC (and Regulation (EU) No 536/2014 when in force) then they are in accordance with GCP and can be accepted.
If you are invited to sign a FDA 1572, this can only be done if a waiver is attached. The sponsor must ask the FDA for a waiver for centers outside US. After consulting the FAMHP earlier this year, we also can agree with a separate ICH-GCP statement to be signed instead of the FDA1572 form + waiver.

6. Source documents

Source data are data contained in source documents. Source documents are the original, initially-recorded documentation of the data. Examples of source documents are hospital records, clinical charts, laboratory reports, radiology reports, subjects' diaries, pharmacy dispensing records,…
Source documentation serves to verify the existence of the subjects and confirms the integrity of trial data.

In order to allow the sponsor's representatives, EC and regulatory bodies to perform trial monitoring, audits, EC review and regulatory inspections, UZ Leuven grants them access to the electronic medical records of UZ Leuven after signing the Electronic Medical Record (EMR) access agreement.
An inspector is by law bound by a duty of secrecy and confidentiality and hence will not be obliged to sign a "EMR access contract".
Copies of source documents can never leave the site.
Exceptionally, after duly escalation, source documents can only leave the site once they have been fully anonymized.

Info

Information

ec@uzleuven.be
www.uzleuven.be/ethische-commissie/onderzoek
Telephone: 016 34 86 00 (between 10 am and 11 am)
EC Research reopens on 30 December 2019