Newsletter
Ethics Committee Research UZ/KU Leuven
Number 20 – April 2023

Dear researchers and team

We wish you all a happy Easter!
With this newsletter we hope to support you in doing high-quality clinical and translational research with respect for the well-being and privacy of each patient and participant.

Ethics Committee Research UZ/KU Leuven

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1. Informing parents about a pregnant child

In studies with children (minors), we sometimes see the following sentence mentioned in the assent form for them: "*We will not tell your parents if you have a positive pregnancy test, without you saying that we can do this.*"

We checked legally whether this sentence is acceptable.

The Patient Rights Act provides that the minor be involved in the exercise of his/her rights taking into account his/her age and maturity (Art. 12, § 2).
Legal doctrine here distinguishes 3 stages of development:

1. the minor is **legally incapable and thus unable** to form and express an opinion (like e.g. newborns);
2. an **intermediate** stage in which the minor is involved in exercising his/her rights but his/her parents still take the necessary decisions;
3. The minor is **capable** of exercising his/her rights independently and deliberately.

It is up to the attending physician to assess on a case-by-case basis what stage the minor is at and therefore to what extent the minor should be involved in the exercise of his/her rights. It is often said that a minor is legally competent from 14 to 16 years of age, but the law itself does not provide an age limit. Other factors will also have to be taken into account (the level of emotional and intellectual development, the scope and nature of the treatment or intervention, personality, mental state, family and social environment, education, etc.).

If the minor is considered to have the capacity to consent, the attending physician may no longer give information to the minor's parents without his/her consent (application of professional secrecy).

As for minors who are in the intermediate stage, in principle, no treatment can take place without parental consent. The follow-up of the pregnancy will therefore only be possible with parental information.
Consequently, it is case by case to determine whether the following sentence in an assent form applies: *"We will not tell your parents if you have a positive pregnancy test, without you saying that we can do this."*

2. English website EC

We would like to inform you that the (external) website of EC Research has been translated into English: https://www.uzleuven.be/nl/ethische-commissie-onderzoek. At this moment the website can be consulted in both Dutch and English. The language can be chosen at the top of the web page.

3. Helpdesk data reporting

As was previously reported on intranet UZ Leuven, there is now a central help desk for requests related to data reporting and quality indicators.
Requests no longer can be sent directly to (an employee of) the MIR, the KWS or LWS helpdesk.

Requests in the central data help desk are followed up and dispatched. This centralized approach thus ensures that questions quickly reach the right person or service.

Furthermore, the central data help desk integrates the procedure for confidential handling of personal data.
This procedure includes different conditions depending on the situation, for example, an additional approval from the ethics committee or a file submitted to the executive management for approval. (See the procedure on the intranet).

4. Clinical Trial Regulation (CTR)

From 31 January 2023, **new** initial interventional clinical trials on investigational medicinal products (**EudraCT studies**) must be submitted according to the Clinical Trial Regulation (CTR). This means that the trial cannot be evaluated by the EC of a participating site. The study will be evaluated by an independent EC, selected by the CT College.
When UZ Leuven is a participating site in a clinical trial, the study must still be submitted to the Clinical Trial Center (CTC) but it will not be evaluated by EC Research. We cannot make exceptions to this. When the study team has questions about this, we encourage to discuss these with the Federal Agency for Medicines and Health Products (FAMHP).

If the study is already running in Belgium and UZ Leuven is added as a participating site, the study can still be evaluated according to the "old legislation" (Clinical Trial Directive, CTD).

5. Suitability of Principal Investigator for clinical trials (CTR)

ECs must evaluate the suitability of investigators in a clinical trial. As pointed out above, ECs will have to evaluate whether the investigator, who is not affiliated with the site, is suitable to perform the clinical trial. A comprehensive and well prepared CV, highlighting your expertise and competences, is crucial to evaluate this suitability.

We also want to highlight that article 49 of the CTR mentions:

> The investigator shall be a **medical doctor** as defined in national law, or a person following a profession which is recognised in the Member State concerned as qualifying for an investigator because of the necessary scientific knowledge and experience in patient care. Other individuals involved in conducting a clinical trial shall be suitably qualified by education, training and experience to perform their tasks.

Article 36 of the Law of May 7, 2017 ("national law") states:

> In accordance with Article 49 of the Regulation, the researcher must be a **medical doctor** within the meaning of the Law on the Practice of the Health Professions, coordinated May 10, 2015. [The investigator may also have the capacity of **a dental practitioner**, within the meaning of the same law, as regards clinical trials related to dentistry.]

Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion. The patient should be informed in a clear and understandable manner. Article 12 of the Law of May 7, 2017 mentions that the member of the research team who conducts the interview (informed consent discussion) shall have the capacity of a **medical doctor or a dental practitioner.** This member may, on his or her own responsibility and under his or her own supervision, entrust a **nurse** with the activities to obtaining informed consent (in accordance with article 46 of the Law of May 10, 2015).

6. Informed consent interview

An important aspect of a clinical trial is that the potential trial participants give their voluntarily informed consent to participate. To give consent, the potential participant needs adequate information. ICH E6 requires that all potential trial participants are fully informed on the clinical trial and are given the opportunity to ask questions.
Informed consent is not only of ethical and legal importance: good communication between the investigator and the trial participant is beneficial for mutual trust and may promote trial compliance.

EudraCT studies

For **EudraCT studies** (interventional clinical trials on investigational medicinal products), conducted under CTR, we already indicated in the previous item of this newsletter (*Suitability of Principal Investigator for clinical trials (CTR)*) that the interview must be conducted by a member of the research team who is a medical doctor/dental practitioner, whereby delegation is only possible to a nurse.
This means that a Clinical Trial Assistant (CTA) who has studied Biomedical sciences may not legally conduct an interview for the purpose of obtaining informed consent in the context of a clinical trial.
The ICF should always be **signed** by the principal investigator himself.

Experiments

For studies being considered **experiments** and covered by the Belgian law of 7 May 2004 (not the CTR), we refer to article 6 of this law. This article only mentions that "the patient should be informed in a clear and understandable manner" but it does not specify what the qualifications of the person providing the information, should be.

Therefore, if the site's consenting process is clearly described (confirming a medical doctor should be readily available to answer any medically related questions, should such a question be raised by the subject during the consent process) and it is obvious that the person to whom the consenting process was delegated, is well trained (and the task was delegated on the delegation log), EC can allow the delegation for conducting the informed consent interview to members of the study team who may not health care practitioners under the Law of May 10, 2015 (e.g. a CTA who has studied Biomedical sciences).
The ICF should always be **signed** by the principal investigator himself.

7. Scientific Integrity Seminar

The application process to get a study ethically approved can seem quite tricky at times. A seminar on scientific integrity was organized by the doctoral program of Psychology and Educational Sciences. In this seminar, the ethical review boards for medical and non-medical human research at KU Leuven are introduced (i.e., Social and Societal Ethics Committee and EC research) and they discuss the privacy check that is required when processing personal data. The procedures of both committees are explained and advice is given for the review process as well as explanations of the PRET tool and the Medical Device Regulation (MDR).

You can find the recording here:
https://kuleuven.mediaspace.kaltura.com/media/Scientific+Integrity+Seminar_+SMEC+%26+GDPR-20230321+without+Q%26A/1_j6bc18sg

8. Medical Device Regulation (MDR)

As of May 26, 2021, the European Regulation (EU) 2017/745 on Medical Devices (MDR) is into force. The MDR sets up the rules for the contents of the application, for the assessment by EU Member States and Ethics Committees and the obligations for sponsors in terms of conduct and reporting. Any instrument, apparatus, appliance, *software*, implant, reagent, material, or another article can be a medical device.

An app, therefore, can also be a medical device. The extensive definition of medical device is given in article 2 of the MDR.
The determination of whether something is a medical device is based on the intended (medical) purpose. The intended purpose describes what the product is designed to do.

On this website, you can do a quick scan to determine if a device or software should be qualified as a medical device: https://cetool.nl/en/medical-device

9. Clinical trials within scope: submission Biobank

In Belgium, human bodily material (HBM) collected within the context of a clinical trial with medicinal product or a trial in which medicines are compared to medical devices, is exempt from the Human Body Material Law. This means that, when the material is collected and used as described in a clinical trial application approved by the FAMHP and the ethics committee, no biobank approval is required, and the study does **not** have to be submitted to the UZ KU Leuven Biobank.

However, if the HBM collected within the clinical trial is used for or intended for future use for another purpose [to study another disease, another treatment, and another drug] than the purpose provided in the approved dossier and informed consent form (ICF), its use is subject to the Human Body Material Law. In that case, the study needs to be submitted to the UZ KU Leuven Biobank for approval and the HBM must be registered at the biobank.


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