Newsletter
Ethics Committee Research UZ/KU Leuven
Number 24 – April 2024

Dear researchers and teams

With this newsletter we hope to assist you in doing high-quality clinical and translational research with respect for the well-being and privacy of each patient and participant.

Happy Easter!

Ethics Committee Research UZ/KU Leuven

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1. Transition of clinical trials from the Clinical Trials Directive (CTD) to the Clinical Trials Regulation (CTR)

As per the guidance on transition of trials authorised under the CTD, only trials that have member states with active sites should be transitioned to the CTR. This implies that it is foreseen that for these sites, the last visit of the last subject, or other trial-specific interventions with the subject specified in the protocol will take place after 30 January 2025. Therefore the trials should be transitioned.

If the clinical trials have not transitioned to the CTR by the end of the transitional period of the CTR, these trials are to be considered as non-compliant with the CTR and sponsors may be subject to corrective measures by member states pursuant to Article 77 of the CTR. Also, no changes, no amendment to the protocol can be done under the CTD for these trials that have not been transitioned by 30 January 2025.

2. Clinical study application

In the context of improvement projects for research support, the registration form for new clinical studies has been modified. The goal is to make this form clearer and more comprehensive for applicants, following the principle of 'first time right', in order to reduce additional follow-ups and email correspondence, and improve turnaround times.

Every new study must be registered using this new registration form.
After registration of the new study and acceptance by the Principal Investigator (PI), an S-number will be automatically assigned. The S-number will remain the unique identifier for further communication about the study.

To expedite the registration process, a subset of registered studies will no longer be processed through CTC, but will instead be directed to the UZ/KU Leuven Biobank or directly to EC Research. This will be done through a background triage and does not require additional actions from the applicants. We ask to thoroughly review the EC website before submitting a study. Our website is updated with the most recent information.

3. International studies

We would like to remind you of the importance of including the name of the Principal Investigator (PI) in the protocol for multicenter studies. Additionally, when engaging in collaborations with other centers, it is crucial to establish roles *ab initio*, including considerations regarding authorship.

4. UZ Leuven: correct name

In our February 2024 newsletter, we explained the correct citation format for KU Leuven. Proper referencing to UZ Leuven is also essential. The aim is to establish uniformity in the way these institutions are referenced. Therefore, the name "Universitaire Ziekenhuizen Leuven" will no longer be used, and in all forms of communication, consistent reference should be made to the official name "UZ Leuven".

When asked what "UZ Leuven" stands for, the response can be "Universitair Ziekenhuis Leuven" (singular) in Dutch and "University Hospital" in English.

You can find more information here.

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5. Opt-out

Any research project involving the processing of personal data must be submitted to EC Research to enable a "privacy check", among other things; this includes retrospective studies.

UZ Leuven engages in scientific research independently as well as in collaboration with **academic or industrial partners**, both of which are essential for maintaining the same high standard of care for everyone.

In cases where scientific studies are conducted outside the public interest, patients are provided with the option to oppose such data reuse through **an 'opt-out' mechanism** applicable to all future uses.

The opt-out option can be communicated through various ways:

- Via the mynexuzhealth app
- Via the online form on the website: https://www.uzleuven.be/uw-patientendossier.
- Via a paper form

Also, when UZ Leuven data is processed in a retrospective study outside public interest, the GDPR questionnaire should be completed and submitted to EC Research. Patients will be informed about the study, via the Mynexuz app under "Projects".

6. Recruitment via intranet

The Ethics Committee should **always** be informed of the means used to announce a study. These include both "traditional" channels (posters, leaflets, etc.) and various forms of advertising via the internet (intranet, website, social media, etc.). The necessary documents must be submitted for approval with the submission dossier.

A call for study participants for an approved study can be made through intranet. This recruitment method must explicitly be submitted to the EC for approval. The advertisement must also clearly mention the study's S-number.

More guidelines about advertisement can be found on the EC website:
https://www.uzleuven.be/en/advertisementrecruitment-clinical-studies-guidelines-ec-research.

7. Patient facing documents

Based on the Question & Answers document provided from the Clinical Trials Regulation (EU) No 536/2014, not all patient facing documents need to be submitted for EC review.
Patient facing documents are defined as documents, other than recruitment material or subject information sheets, presented to clinical trial participants during the conduct of the clinical trial.
Patient facing documents that are linked to the endpoints of the clinical trial shall be provided together with the protocol in part I of the clinical trial application, in the same language as the submitted Informed Consent Forms (ICFs). These documents will be assessed during the part I assessment.

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Other patient facing documents, other than documents that are linked to the endpoints of the clinical trial, should be submitted in Part II.

Here is a list of patient-facing documents that sponsors are **not required** to submit (no EC review necessary):

- Insurance certificate in language of the patient
- Patient cards, trial identification cards
- Instructions on how to use a tablet or phone to complete e.g. e-questionnaires
- Digital vouchers/cards used to reimburse participants

You can find the advice also on the BAREC website: https://barec.be/advice-barec-patient-facing-documents/