Newsletter
Ethics Committee Research UZ/KU Leuven
Number 23 – February 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.

Ethics Committee Research UZ/KU Leuven

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1. Transfer of artificialized and extracted material from a researcher at KU Leuven to a third party.

EC, in collaboration with Leuven Research & Development (LRD) and the Biobank, has developed a new protocol template. This protocol is specifically designed for the transfer of artificialized and extracted material from a researcher at KU Leuven to a third party. The protocol can be found on the EC-website: https://www.uzleuven.be/en/ethics-committee-research/study-human-body-material-secondary-use

This protocol requires close interaction between both parties: the 'provider-scientist' (the researcher from KU Leuven) and the 'recipient-scientist' (the receiving researcher). Certain essential data must be provided by the 'provider-scientist', while other information needs to be submitted and supplemented by the 'recipient-scientist'.

2. eConsent in REDCap

In the newsletters of November 2020 and April 2022, we provided guidelines on the use of eConsent. Additionally, we would like to refer you to the CTC website (https://gbiomed.kuleuven.be/english/ctc/ – "Data Management" – "What is REDCap" - "eConsent").

It is possible to use eConsent through REDCap for academic studies, after EC-approval. For further assistance, please contact the CTC Data Management team, they provide REDCap user support.

3. KU Leuven: correct name for the university in publications

KU Leuven is the only correct name for the university and should always be mentioned first.
'Universiteit Leuven' or 'University of Leuven' must not be used. 'Catholic University of Leuven' can be used, if preceded by 'KU Leuven' when reference to the Catholic identity of KU Leuven is of decisive importance in a given context. For more information, see https://research.kuleuven.be/en/associatienet/output/identification.

4. EC can contact PI's for more information about their study with IMP

In the past, EC used to invite researchers to elaborate on their studies and address questions during its committee meetings, particularly for those involving research with medicinal products due to the complexity of such studies.

However, this practice was discontinued since the implementation of CTR as the EC affiliated with UZ Leuven is no longer permitted to evaluate studies conducted within UZ Leuven itself. This decision aligns with the requirement for an evaluating EC to maintain independence from the site. Despite this

restriction, CT-College has recently confirmed that the EC's are allowed to contact Principal Investigators (PIs) directly to ask for some clarifications.

The College does not consider reaching out to PIs as a breach of EC independence, provided it is properly documented in meeting minutes and complies with Article 11 of the Royal Decree of 9 October 2017. Consequently, also researchers from UZ Leuven may receive invitations from other EC's to present and discuss their studies.

5. Umbrella Protocol for Human Bodily Material (HBM) collection

We want to give you some information about this type of umbrella protocols. It is a protocol used to establish a collection of human bodily material (HBM) for use in scientific research. It can involve both secondary use and primary use of HBM :

- HBM that was initially collected for use in scientific research within previous S-number(s) (**left-over HBM**)
- HBM that was initially collected for **diagnostic** purposes but is no longer needed for that purpose (**residual** HBM).
- HBM newly collected for use in scientific research

The general principle contained in the Law of December 19, 2008 (Law on the Acquisition and Use of Human Biological Material for Medical Application in Humans or Scientific Research (Law on HBM)) is that the collection and (primary and secondary) use of HBM requires the explicit written consent of the donor. Primary use is defined in the Law on HBM as: "*Any use of HBM for a purpose for which the donor has explicitly consented to in the context of the collection of the material*". Secondary use is defined in the Law on HBM as: "*Any use of HBM for a purpose other than that for which the donor has given his/her consent in the context of the collection of the material.*"

For the use of residual HBM, an exception to the rule of explicit written consent exists, i.e. an "opt-out" applies pursuant to the Law on HBM, meaning that, if the donor did not explicitly object to the use of the HBM for scientific research, after he/she has been informed about such potential use of his/her HBM, the donor's consent is deemed to be given. Such **opt-out** eliminates the need for an explicit consent in the form of a specific ICF. Patients will be informed through the patient brochure (https://www.uzleuven.be/nl/raadpleging-en-opname) about their option to opt-out of the use of their HBM for scientific research. If no opt-out is executed, transparency about the use of HBM will be organized through "flagging" of patients in the patient dossiers with a new S-number, and information of such use will be conveyed through Mynexuzhealth, ensuring a seamless and transparent process.

Every future research project utilizing HBM from this collection, along with corresponding clinical information, will require a separate approval process with the Ethics Committee Research UZ / KU Leuven (EC Research). Each project will be treated as a 'user protocol' with its own designated S-number.

In this context we also refer to the newsletter of EC from December 2020 regarding requests for secondary use of (personal) data and/or samples. Secondary use of (personal) data and/or samples that have been collected in prior prospective academic studies with UZ Leuven as sponsor and which researchers now want to share with other research partners (academic and/or commercial) in the context of new scientific research projects, always require an approval of EC Research pursuant to the Law on HBM, even if in some cases consent has already been obtained from the participant to the original study for the sharing of his/her data and/or samples in the context of new scientific research projects.

Finally, please always register your "umbrella study" at the UZ Leuven clinical trial center (do not forget to indicate the biobank as a supportive department on the CTC-registration form, regardless of the storage location of the HBM).
Once an internal S-number has been assigned to your study, you can submit an application to EC (ec@uzleuven.be) and the biobank (wbb@uzleuven.be).

6. New members EC

EC Research warmly welcomes new members to its committee:

- Prof. Francesca Bosisio
- Prof. Catherine Cassiman
- Prof. Heleen Delbeke
- Dr. Ellen Deleus
- Prof. Frederik Nevens
- Dr. Kamiel Verbeke
- Prof. Kristin Verbeke

We look forward to their valuable contributions to the committee.

7. Trial at a glance

On 3/9/2020, the general assembly of BAREC (Belgian Association of Belgian Research Ethics Committees, https://barec.be/) agrees on the following statement regarding the section "trial at a glance" of the ICF template for interventional clinical trials with IMP on adult patients:
BAREC advices its members to check thoroughly each informed consent form (ICF) and especially the part "Trial at a glance" which must meet all requirements as indicated on the "Model ICF for interventional clinical trials with IMP on adult patients" available on the website of the Clinical Trial College. Not meeting

these requirements should result in a negative opinion as far as the research ethics committee (REC) is concerned.

At the Symposium of BAREC on December 9, 2023, an updated decision was reached regarding the 'trial at a glance' section in the ICFs. BAREC agrees that a 'trial at a glance' section is deemed necessary for all ICFs related to adult participants, regardless of the study type and regardless of whether it concerns patients or healthy volunteers.
It is crucial for a participant, who is often not acquainted with the design of studies and the complex terminology related to legal and regulatory aspects, to fully understand the implications of their participation. On the other side, this provides professionals with the advantage of quickly gaining insight into the study.

8. Annual progress reports EudraCT studies

We already stated in previous newsletters (e.g. October 2022) the importance of submitting an annual progress report. From 31 January 2025, all trials will be running according to the Clinical Trials Regulation (CTR) rules. If you still have a clinical trial which is not yet transitioned to the CTR, you should submit an annual progress report on time to extend the EC approval. In case you have submitted your transition in CTIS, but not yet received an approval, you are expected to submit an annual progress report, if deemed necessary.

9. Compensation of contraception

BAREC has issued an advice concerning the compensation of contraception. The mandatory or recommended use of contraception should generally be regarded as study-related. This implies that sponsors are expected to cover the costs associated with obtaining and using contraception methods, ensuring that participants are not burdened with these financial obligations. The study-related contraception should be either reimbursed (if paid in advance by the participant) or compensated for (if a reasonable fixed lump-sum has been agreed upon). Not meeting these requirements for studies submitted under the framework of CTR/MDR/IVDR, should result in a negative opinion as far as the research ethics committee (REC) is concerned. For more information we refer to the BAREC "Guidance on fair compensation of subjects for their participation in clinical research in Belgium".

10. Sponsor change

When the sponsor of an approved study changes, this change must be submitted to EC for approval (via ec@uzleuven.be). Since this change also has contractual implications, it should also be submitted to the Clinical Trial Center (CTC). Study amendments must be submitted to CTC via online registration: https://www.uzleuven.be/en/ctc/register-an-amendment.

The digital registration allows for more efficient triaging and routing of the amended information for processing, by the relevant staff.

Info

ec@uzleuven.be

https://www.uzleuven.be/nl/ethische-commissie-onderzoek

Telephone: 016 34 86 00 (between 10 am and 11 am)