Newsletter

Ethics Committee Research UZ/KU Leuven

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Happy Easter!

Dear all,

At EC Research, our core mission is to protect the participants involved in your studies while supporting you throughout your research journey.

We are dedicated to ensuring the safety, well-being, dignity, rights, and privacy of both patients and healthy volunteers in clinical research. As an independent advisory body, we prioritize the welfare of participants above all.

Best of luck with your research projects.

Kind regards,
EC Research

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New version Good Clinical Practice (GCP) Guidelines

On January 6th 2025 the long-awaited revision 3 of Good Clinical Practice Guidelines (GCP r3) was adopted and published on the ICH website (www.ich.org). The members of the RUZB-workgroup for clinical research (RUZB = Raad Universitaire Ziekenhuizen België) are working diligently to update the GCP-eLearning which should be available shortly. Meanwhile, it is recommended that study teams and investigators will document self-training on the study-specific training logs. Once available, all clinical research personnel and investigators will be required per UZ/KU Leuven policy to complete the eLearning. The resulting training certificate will be validated by TransCelerate and valid for 3 years.

Reconsent

Ensuring that participants remain fully informed throughout a clinical trial is a fundamental principle of GCP. In some cases, obtaining reconsent - renewed informed consent - is necessary to uphold ethical and regulatory standards.

According to ICH GCP E6, reconsent should be obtained when:

- **Significant changes occur in the study**, such as:
  - New information about risks or benefits.
  - Protocol modifications that may affect participation.
  - The availability of new treatment options.
- **The participant no longer meets the original consent conditions**, for example: a minor reaches adulthood and must provide consent themselves.

More information can be found in the GCP Guidance itself:

- Section 4.8.2: Informed consent must be freely given before trial participation.
- Section 4.8.3: Investigators must comply with regulatory and ethical requirements.
- Section 4.8.10: Participants must be informed of any new relevant information that could affect their willingness to continue.
- Section 4.8.11: Participants should never be unduly influenced to remain in a trial.

Maintaining ongoing informed consent is not just a regulatory requirement but also an ethical obligation to ensure patient autonomy and safety.

When new information becomes available that may affect a participant's willingness to continue in a clinical trial, it is crucial to document the communication of this new information.

Additionally, any revised written informed consent forms and related information must receive prior approval from EC before being used.

ICF templates

We are pleased to announce that new ICF templates are available on the BAREC website (https://barec.be/documents/), on our website (https://www.uzleuven.be/en/ethics-committee-research/explanatory-notes/drawing-informed-consent-form-icf) and on the website of CT-College. You can find here:

- Interventional clinical trials with an investigational medicinal product on adult patients (adapted version in Dutch, French, English)
- Clinical investigations for adult patients involving a medical device (adapted version in Dutch, French, English)
- Interventional clinical trials with IMP on adult healthy volunteers (new template, in Dutch, French, English. This template is prepared in consultation with Healixia).

These templates have been approved by the Board of CT-College on 24/01/2025.

Please note that the use of the templates will become **mandatory** when submitting initial study applications for new clinical studies as of **August 1st 2025**.

We hope that these new templates will support you in your work and contribute to a more efficient evaluation process.

External research requests

In light of the growing number of students in the Group of Biomedical Sciences and the increasing demands on our healthcare teams and patients, UZ Leuven is implementing a more restrictive approach to external research requests that may put an additional burden on UZ Leuven patients and healthcare personnel. Our priority remains providing optimal patient care while supporting the research of our students and researchers.

If you receive requests from other universities regarding such projects, the following statement can be used as a response:

"Gezien het toenemend aantal studenten in de groep Biomedische Wetenschappen en de groeiende belasting op onze zorgteams en patiënten, willen we zorgvuldig omgaan met verzoeken voor masterproeven die uitgevoerd worden bij de patiënten en/of zorgverleners van UZ Leuven. Onze prioriteit blijft het bieden van optimale zorg aan onze patiënten en het ondersteunen van onze studenten en onderzoekers.
*Om deze redenen hanteren we een meer restrictief beleid voor **externe onderzoeksaanvragen**. Voor de specifieke masterproef/studie waarvoor navraag is gedaan, hebben we besloten geen toestemming te verlenen, gezien de bijkomende belasting voor ons personeel en onze patiënten."*

Ensuring continuity in sample collections

Proper management of sample collections is crucial for ensuring compliance, traceability, and long-term research integrity. A PI change should be proactively and timely implemented to guarantee continuity in the oversight of both ongoing studies and post-study sample storage.
To uphold these responsibilities, the PI must commit to fulfilling the biobank agreement, ensuring full traceability of human biological material (HBM) for the agreed storage duration—even after sample collection has stopped.
The PI must also designate a qualified researcher to take over custodianship of the HBM collection if their research responsibilities are temporarily or permanently discontinued.

Master's theses that are related to another study that has been evaluated by EC Research

Every student within the Biomedical Sciences group must assess, using a set of questions, whether their master's thesis requires further ethical review. The Education-Support Committee (OBC) is responsible for ensuring that the evaluation process for master's theses aligns with the assessment conducted by EC Research UZ/KU Leuven.

OBC will be able to assess low-risk master's theses.

Master's theses falling under the following categories must upfront be submitted to EC Research for review:

- Master's theses that are related to another study that has been evaluated by EC Research (and therefore has an S-number)
- Studies that prospectively collect data from living individuals through medically related interventions or actions
- Studies using human biological material
- Studies involving collaboration with an external organization, unless the collaboration is limited to participant recruitment and does not involve interaction with patients, human biological materials, or personal data.

Use of track changes for amendments

When submitting an amendment to EC, we request to use track changes to indicate the changes. For this, please start from the clean version of the previously approved version. In this way, the modifications regarding the amendment are clearly visible. We discourage the use of highlight as removals and changes are not visible in this way.

Policy Research Data Management

A new version of the KU Leuven Policy for Research Data Management (RDM Policy) was approved by the Academic Council on 25-02-2025 and has come into effect. UZ Leuven also endorses this policy. The policy applies to all research data processed at KU Leuven and UZ Leuven, with research data defined according to the Open Data Directive. The policy aims to ensure that research data are managed according to the highest quality standards, in the interest of scientific integrity, and with a focus on the reproducibility or verification of research results and the potential reuse of research data.

The policy consists of seven core principles, which are explained with information and guidance for practical implementation. A key addition is **Principle VII**, which focuses on making research data available for reuse, ensuring that data are managed in accordance with the international **FAIR data principles**. In this context, **KU Leuven RDR (Research Data Repository)** and the **UZ/KU Leuven DAC (Data Access Committee)** play a crucial role in facilitating the sharing of research data in line with legal and ethical regulations and international standards. **Principle VII will take effect for research projects starting from October 1, 2025.**

Full policy text:
[NL] https://www.kuleuven.be/rdm/nl/beleid/rdm-beleid-ku-leuven
[EN] https://www.kuleuven.be/rdm/en/policy/policy

Blind Carbon Copy

When sending general emails—such as recruitment messages or study-related updates—it is best to use BCC (Blind Carbon Copy) instead of CC. This helps protect recipients' privacy by keeping their email addresses hidden from others.
Using BCC ensures compliance with data protection regulations and maintains professionalism in communication.

Principal Investigator (PI) and responsibilities

Being a Principal Investigator (PI) in a study comes with real responsibilities. As the lead researcher, you are accountable for the study's design, execution, integrity, and compliance with ethical and regulatory standards.

An investigator is defined in GCP as:
"A person responsible for the conduct of the clinical trial, including the trial participants for whom that person has responsibility during the conduct of the trial. If a trial is conducted by a team of individuals, the investigator is the responsible leader of the team and may be called the principal investigator. Where an investigator/institution is referenced in this guideline, it describes expectations that may be applicable to the investigator and/or the institution in some regions. Where required by the applicable regulatory requirements, the "investigator" should be read as "investigator and/or the institution."

Taking on this role implies committing to the study's success and ensuring that all aspects are conducted responsibly.

Delegation log

The investigator should also ensure that a record is maintained of the persons and parties to whom the investigator has delegated trial-related activities. Documentation of delegation should be proportionate to the significance of the trial-related activities. This includes anyone conducting tasks that go beyond standard care, such as study-related blood draws or data collection.

When conducting a study, having enough qualified staff is crucial. Everyone performing study-related procedures must be properly trained and training must be documented. This means that even if residents-in-training (ASO) or nurses are capable of performing procedures like blood draws, they cannot do so unless they are officially delegated. Adhering to these regulations is essential to ensure compliance and integrity of your study. Keep in mind that nurses in clinical care already have a heavy workload and cannot be expected to take on study-related tasks unless properly planned and agreed upon.

Additionally, when submitting your study to EC, you must specify globally in the protocol who will be conducting the procedures. This ensures transparency and compliance with regulatory requirements.