Newsletter

Ethics Committee Research UZ/KU Leuven

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Dear all,

At EC Research, we are committed to safeguard the rights, dignity, safety, and well-being of all participants involved in clinical research, while supporting you throughout your research activities. As an independent advisory body, participant welfare and ethical integrity remain our guiding principles.

We say goodbye to Jean-Jacques Derèze and would like to express our sincere gratitude for the excellent collaboration over the years. We wish him every success in his future endeavors. At the same time, we are pleased to welcome Erik Mannaert.

With the arrival of spring, we hope this season of renewal brings fresh energy and inspiration to your work. We also take this opportunity to wish you a joyful Easter. We wish you every success in your ongoing and future research endeavors.

EC Research

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ICH-GCP E6 (R3): New eLearning Available

Following the communication in our previous newsletter, in which we announced the upcoming eLearning on the updated ICH E6(R3) Good Clinical Practice guidelines, we are pleased to inform you that this training is now available via intranet (Leercentrum).

Obtaining an ICH-GCP E6 certificate is mandatory for all clinical investigators, Clinical Trial Assistants (CTAs), and staff members of the Clinical Trial Centre (CTC) and the Ethics Committee. Upon successfully completing the knowledge assessment with a score of at least 80%, participants receive an internationally recognized ICH-GCP E6 (R3) certificate. This certificate is valid for three years and is required by regulatory authorities and Ethics Committees as proof of adequate knowledge of the principles and standards of clinical research.

We encourage all relevant staff who have not yet obtained this certification to complete the training in a timely manner to ensure continued compliance with the updated regulatory requirements. Obtaining the GCP certificate through another validated assessment is also acceptable.

Access to medical data: What are Insurance companies allowed to see?

Questions may arise about whether insurers can access medical records or results from clinical studies. Below, we clarify what can be shared, the role of the patient in this process, and the legal boundaries that apply. More information can also be found on the website: https://www.uzleuven.be/nl/media/9ebfb257-acbe-4ab1-bf27-afff64ca205d/toegang_medisch_dossier_verzekeringsmaatschappijen_10feb2026.pdf

For health-related insurance, such as in cases of illness or death, insurers require certain medical information to properly conclude but also manage an insurance policy. This information allows them to determine coverage, calculate premiums, and handle any reimbursements or benefit payments accurately. It is therefore important that relevant information is disclosed fully and honestly to avoid problems later on. At the same time, patients remain in control of their data: medical information may only be shared with the insurer or the insurer's medical advisor (a physician working for the insurer) with the patient's consent, as laid down in the GDPR and the Patients' Rights Act. Insurers do not have direct access to medical records or other medical databases.

In practice, information is collected through a questionnaire covering health status, lifestyle, and medical history. If necessary, additional information may be requested via a medical certificate from the treating physician, a medical examination, or a consultation with a medical advisor. The latter may only provide limited and relevant medical advice, not full medical details. Genetic data may never be shared with an insurer. However, if a genetic condition has been formally diagnosed and forms part of the patient's current health status, it must be disclosed. Patients may refuse to undergo examinations or share certain information, and physicians may invoke professional secrecy. Such refusals may have consequences, such as being unable to obtain insurance coverage or receive compensation.

Health insurance funds likewise do not have access to complete medical records. They process only the data strictly necessary for reimbursement and control purposes, using standardized certificates and codes provided by healthcare professionals.

APR Reporting: Don’t Overlook Protocol Deviations and Violations

For studies conducted under the Law of 7 May 2004 on experiments involving the human person, the submission of an Annual Progress Report (APR) is mandatory (https://www.uzleuven.be/nl/ethische-commissie-onderzoek/goedgekeurde-studie-ec-onderzoek-aanvullen/vorderingsrapport-indienen-bij-ec-onderzoek). This report should provide a comprehensive and accurate overview of the current status of the study. Appendix 3 of the report is specifically intended for documenting protocol violations and/or deviations that occurred during the reporting year.

In practice, it is observed that this section is frequently left incomplete. We would like to emphasize that all deviations and violations are expected to be reported transparently. This includes not only serious breaches, but also (frequently occurring) minor deviations. Below are several examples to illustrate which kind of minor and major issues should be reported.

Protocol deviations are typically unintentional or less critical departures from the protocol. Examples include failure to perform all planned procedures (e.g. a missed blood sample or an incomplete questionnaire), delays in staff training documentation or technical issues (e.g. temporary device malfunction resulting in missing data).

Protocol violations, on the other hand, are deviations that may impact participant safety or data integrity. Examples include inclusion of an ineligible participant, unauthorized changes to the protocol, failure to report a serious adverse event (SAE) in a timely manner, or structural and repeated non-compliance.

We kindly ask to ensure accurate and complete reporting in the APR for each reporting period. Thorough documentation in Appendix 3 is essential to safeguard participant safety, uphold data quality, and meet regulatory requirements.

Decision Tree: submitting to EC or SMEC?

To support researchers and study teams in submitting their project to the appropriate ethics committee, a decision tree is available to clarify the respective scope of EC Research and SMEC.
The Social and Societal Ethics Committee (SMEC) evaluates research for ethical approval in the humanities and behavioral or social science research traditions, which are not considered to be an experiment. In addition, protocols in engineering, natural or life sciences may also be reviewed by SMEC. SMEC is authorized to assess research involving human participants provided that:

- the study does not fall under the Belgian Human Subject Experiments act (i.e. the “Experiments act” of May 7, 2004),
- there is no involvement of UZ Leuven patients, patient data and/or UZ Leuven staff, and
- the research does not take place on the UZ Leuven campus.

It is important to note that studies involving the collection or use of human body material must always be submitted to EC Research, due to the involvement of the Biobank, even if the study otherwise appears to fall within the scope of SMEC. In such cases, submission to SMEC is not appropriate, and EC Research should be contacted instead.
More information on SMEC and access to the decision tree can be found here https://www.uzleuven.be/en/ethics-committee-research/smec. We strongly encourage all study teams to consult this tool early in the study preparation phase to avoid delays or incorrect submissions. If there is any doubt about the correct ethics committee, early consultation is recommended to ensure a smooth and compliant review process (via ecstaf@uzleuven.be or via an appointment at the Clinical Research Office: https://gbiomed.kuleuven.be/english/ctc/intern/ctc-office/CTCOffice). Be aware that it is not always clear upfront whether the experiments act applies, and that such a decision is made by a plenary EC. EC Research can also give an advice if studies do not resort under the experiments act.

What is (and is not) allowed for students when accessing KWS in the context of research?

Students are regularly involved in research projects within UZ Leuven. Access to centrally managed systems containing health data (KWS) is strictly regulated and strongly depends on both the student's status and the phase of the research.

A clear distinction is made between **qualified** and **non-qualified** students. A student is considered qualified if they hold a bachelor's degree and are enrolled in a master's, advanced master's, or doctoral programme leading to a healthcare profession, or in the clinical graduation track BMW. In addition, all students must meet the same basic requirements as other users: they must be registered in PeopleSoft HR, be bound by professional confidentiality or contractual non-disclosure obligations, and have completed training on privacy and data protection.

Access to KWS for research purposes is assessed across three phases: **feasibility**, **pre-screening**, and **post-inclusion access**.

During the **feasibility phase**, when the viability of a study is explored and no protocol is yet in place, students are never granted access to KWS, regardless of their status.

In the **pre-screening phase**, where patients are assessed against inclusion and exclusion criteria based on a protocol, within the context of an approved S- or MP-number, access is only granted in exceptional cases. Only qualified students may be considered, and only if they are explicitly listed in the study-specific extended study access (registered in PeopleSoft CTCKWS: Study Extended Access). In addition, patient selection must either be carried out in advance by someone with a therapeutic relationship with the patient or be based on a sufficiently strict pre-programmed query. Non-qualified students are not granted access at this stage.

After study participants have been included (following Ethics Committee approval and, where applicable, informed consent), specific rules apply. Within clinical studies, qualified students may access KWS if they are part of the research team and registered in the extended study access. For research projects within an educational context, the cascade principle applies. Students are first encouraged to design their research in a way that allows them to work with automated queries on structured KWS data that return only pseudonymised results. If this is not sufficient, they may link their work to an ongoing clinical study with an approved S-number. Only if neither option is feasible may qualified students with an approved MP number be granted direct access to the records of included participants. Non-qualified students, within this cascade, can only work with pseudonymised, automatically generated results and are never granted direct access to KWS.

These rules aim to strike a balance between high-quality education and research on the one hand, and the protection of personal data on the other. They also highlight the importance of a well-considered research design, particularly when students are involved. It is important to take these restrictions into account when writing the protocol. For more information on access to KWS in general, please consult the following site: https://wiki.uz.kuleuven.ac.be/display/public/muzlidoc/Gezondheidsgegevens+en+onderzoek#Gezondheidsgegevensenonderzoek-Detoegangtotpersoonsgegevensmetredenonderzoek

Data brokers: conditions for collaboration

The Data Protection Board of UZ Leuven has established a set of transparent criteria to serve as a benchmark for assessing requests related to the valorisation of patient data through data brokers. As a general rule, such requests will receive a negative recommendation unless all of the conditions outlined below are met. Collaboration can only be considered where these conditions are fulfilled cumulatively.

1. Initiative and governance by UZ Leuven

Collaborations may only be initiated by UZ Leuven. The data broker acts exclusively on behalf of UZ Leuven in the capacity of a processor or sub-processor, without any rights to reuse the data or resulting outputs. The broker is not permitted to enter into direct contractual relationships with external controllers.

2. Demonstrable added value

The involvement of a data broker is justified only where the broker provides clearly identifiable added value, such as specialised analytical capabilities or expertise that are not available within UZ Leuven, for example due to technical limitations or capacity constraints.

3. Clear and well-defined purpose

Each collaboration must pursue a specific and clearly defined purpose that aligns with UZ Leuvens core mission. This purpose must be explicitly documented in the agreement and reflected in the applicable GDPR provisions. Open-ended or vaguely defined purposes are not acceptable.

4. Preservation of research autonomy

The collaboration must not limit UZ Leuvens ability to conduct its own research using the processed data or the results generated. Any remuneration related to the secondary use of data must be agreed exclusively between UZ Leuven and the controller. While UZ Leuven may remunerate the data broker for services rendered, the reverse—payment in exchange for the sale of data—is, in principle, not permitted.

5. Contractual accuracy and balance

All contractual arrangements must accurately reflect the factual circumstances and ensure a balanced allocation of responsibilities and liabilities. This applies equally to intellectual property provisions and to GDPR roles and obligations. Any party seeking to generate intellectual property must also be prepared to assume the corresponding responsibilities, including those relating to GDPR qualification and sponsorship.