Newsletter

Ethics Committee Research UZ/KU Leuven

Number 33 - October 2026



Dear all,

As autumn sets in, we are pleased to share the latest edition of our newsletter, bringing together practical updates, reminders, and points of attention relevant to clinical research. As the research and regulatory landscape continues to evolve, staying informed about current requirements and procedures remains essential. This edition covers key aspects across the research lifecycle, from study preparation and submission to data management, safety reporting, and communication with participants.

We hope these updates will help you navigate the ethical, regulatory, and administrative requirements of your daily research practice with greater clarity and confidence.

The Ethics Committee for Research would like to extend its sincere appreciation to Prof. Dr. Laura Van Gerven for her dedicated service and valuable contributions as committee member. At the same time, we are pleased to welcome several new members to the committee: Dr. Saartje Uyttebroek, Prof. Dr. Fréderic Van der Cruyssen, Prof. Dr. Mostafa EzEldeen and dr. Dirk Vander Mijnsbrugge. We look forward to their involvement and valuable contributions to the ethical review of scientific research. We wish them every success in their new role and are confident that their expertise will further strengthen the committee's work.

EC Research

Members: Dominique Bullens, Ariel Alonso Abad, Pascal Borry, Francesca Bosisio, Guy Bosmans, Catherine Cassiman, Valerie Christens, Ellen Deleus, Erwin Dreesen, Lut De Groote, Theresia De Fraye, Jan de Hoon, Aernout De Raemaeker, Lia De Wilde, Mostafa EzEldeen, Dorien Fierens, Maarten Ganne, Marie Gilliot, Rik Gosselink, Kelly Hoogeveen, Walter Janssens, André Loeckx, Koen Luyckx, Erik Mannaert, Heleen Marynissen, Frederik Nevens, Sien Ombelet, Marleen Renard, Peter Sinnaeve, Karin Sipido, Anne Smits, Mathijs Swaak, Anne Uyttebroeck, Saartje Uyttebroek, Marilien Vandeputte, Fréderic Van der Cruyssen, Dirk Vander Mijnsbrugge, Veerle Vanparys, Frank Van Calenbergh, Ben Van Calster, Bart Van der Schueren, Katelijne Van Overwalle, Kristin Verbeke, Gregor Verhoef, Minne Casteels
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Winter Clock Stop 2026 - 2027

Please note that a winter clock stop will be in effect from 21 December 2026 through 2 January 2027. Submissions received during this period will be assigned a validation date of 4 January 2027. We encourage investigators to take this timeline into account when planning their submissions.

Frequently Asked Questions (FAQ)

Given the continuously evolving and often complex nature of the scientific and medical research landscape, we would like to draw your attention to our FAQ webpage, which is updated regularly to reflect some recent guidance and requirements. We therefore encourage researchers to consult this webpage periodically to stay informed of any relevant developments and recommendations from EC. https://www.uzleuven.be/en/ethics-committee-research/frequently-asked-questions . Before contacting EC with a question, we kindly encourage you to consult the FAQ page, as you may find the information you are looking for straight away. For questions not covered in the FAQ, our team will be happy to help.

Use of data and samples following withdrawal of informed consent

EC has developed a guideline regarding the handling of personal data and biological samples (human body material) of study participants who withdraw their consent to participate in a prospective UZ Leuven study that relies on the legal basis of public interest for the processing of personal data: https://www.uzleuven.be/nl/media/49f1e9b4-198d-4dd9-bb1a-7fdc56e013d7/nota_gebruik_data_en_stalen_na_intrekking_toestemming_19mei2026.pdf. The guideline also covers deferred consent.

In conclusion: participants retain the right to withdraw from research at any time. However, withdrawal from participation does not automatically require the deletion of previously collected data or the destruction of biological samples already obtained.

For studies conducted on the legal basis of public interest, previously collected data and samples may, under specific conditions, be retained where necessary to preserve the scientific integrity, validity, safety, and regulatory compliance of the research. These consequences must be transparently explained in participant-facing documents and clearly reflected in the study protocol.

Reminder: study team documentation and GCP training requirements

A well-documented and appropriately qualified study team is an essential component of Good Clinical Practice (GCP) and quality study conduct. The composition of the study team should be clearly defined and kept up to date throughout the duration of the study. Each team member's role and responsibilities should be adequately documented, and the delegation log should accurately reflect all study-related tasks delegated by the principal investigator. We would like to emphasize that ASO's (residents in training) who perform any study act should also be on the delegation log.

EC further confirms that GCP training is required for every investigator involved in the conduct of a study. It is the responsibility of the PI to verify that all study team members hold a valid GCP certificate and remain compliant with applicable training requirements. We also recommend that GCP training be included in each team member's CV, together with the date the certificate was obtained and the name of the organising institution.

We kindly ask investigators to take these requirements into account when preparing and submitting future study applications, and to ensure that study team documentation remains complete, accurate and up to date throughout the study lifecycle. Please note that EC should be kept informed of any changes to the study team during the course of the study via an amendment.

New Data Protection Board (DPB) Submission Procedure

Please note that the Data Protection Board (DPB) has introduced a new submission procedure for DPB dossiers. As of now, new DPB applications must be submitted exclusively through an online submission form. Submissions by email and the previous PDF-based application process are no longer accepted.
The online application form is available via the following link: https://www.uzleuven.be/nl/aanmelding-nieuw-dossier-data-protection-board-dp-nummer-gdpr-vragenlijst.

Please be aware that it is not possible to save a partially completed submission. Therefore, applicants are advised to gather all required information before starting the online questionnaire. The PDF form will remain available as a reference to help prepare the necessary information.

For questions or technical difficulties, please contact the DPB team at **dpb@uzleuven.be** or **+32 16 34 49 10**.

Which samples must be registered in the new Biobank software?

The UZ/KU Leuven Biobank is currently implementing a new sample registration software, **MBioLIMS**. This software will provide a comprehensive overview of all samples that are subject to the Belgian Biobank law and therefore require Biobank approval as well as an overview of all samples stored in the Biobank's central storage facilities. The Biobank team is currently onboarding research groups into MBioLIMS. Each laboratory will receive training and guidance on the use of the software to ensure accurate and consistent sample registration.

In this context, it is evidently important to know which samples must be registered in MBioLIMS. A sample must be registered in MBioLIMS when at least one of the following conditions applies:

- The sample is subject to the Belgian law on human body material for scientific research and therefore to UZ/KU Leuven Biobank approval.
  - Irrespective of whether or where the samples are stored before use.
- The sample is stored in the Biobank's central storage facilities (= the cryotheques and the freezer room in building O&N4 levels 2 and 3).
  - Irrespective of whether it is human or non-human and irrespective of whether Biobank approval is required. Therefore it is possible that samples that are not subject to the Belgian law on human body material for scientific research are registered in MBioLIMS.

Biobank approval for a study collecting and/or using human body material for research can be obtained by submitting the study through the online study registration form (https://www.uzleuven.be/en/register-a-study). More information on when samples are subject to the Belgian law on human body material or about the MBioLIMS system and the onboarding process and can be found on the biobank website (https://gbiomed.kuleuven.be/biobank).

"Annual Safety Reporting under the Clinical Trials Regulation

For clinical trials conducted under Regulation (EU) No 536/2014 (Clinical Trials Regulation, CTR), the sponsor is required to submit an **Annual Safety Report (ASR)/Development Safety Update Report (DSUR)** on the safety of the investigational medicinal product(s) (IMPs) used in the trial. The ASR/DSUR provides a comprehensive and accurate overview of the evolving safety profile of the IMP(s) and supports the ongoing assessment of the benefit-risk balance of the clinical trial.

For academic clinical trials sponsored by **UZ/KU Leuven**, responsibility for preparing and submitting the ASR/DSUR lies with the UZ/KU Leuven study team. A template for preparing the ASR/DSUR is available on the CTC website: ASR/DSUR template .

The ASR/DSUR is prepared **annually**, starting from the first authorization of the clinical trial and continuing until the end of trial. The reporting period covers **exactly 12 months**, ending at the applicable **data lock point (DLP)**. The ASR/DSUR must subsequently be submitted via the Clinical Trials Information System (CTIS**) within 60 days of the DLP**.

Example: If the initial clinical trial authorization was granted on 1 January 2025, the first annual reporting period runs from 1 January 2025 through 31 December 2025, with a DLP of 31 December 2025. The ASR/DSUR should be submitted via CTIS within 60 days of this DLP. The following ASR/DSUR will cover the subsequent 12-month period.

A CT admin user can assign the appropriate **ASR submitter access** in CTIS to the study team member responsible for the submission.

For technical issues with CTIS, study teams may contact **ctc@uzleuven.be**.

Timely and accurate annual safety reporting is a regulatory obligation under the CTR. Study teams are therefore responsible for ensuring that the ASR/DSUR is prepared and submitted within the applicable regulatory timeline.

Following submission, the relevant authorities may assess the ASR/DSUR and the associated reporting period. If clarification or additional information is required, a Request for Information (RFI) may be issued through CTIS.

Failure to comply with the requirements for annual safety reporting may result in regulatory follow-up, including corrective measures or audits.

For substantive questions regarding safety reporting and ASR/DSUR preparation, study teams may contact **ctc.safety@uzleuven.be**."

KWS Flagging and Mynexuzhealth

Several recent questions we received at EC have highlighted uncertainty regarding the requirement to flag patients in KWS, and the associated patient information flow via Mynexuzhealth for retrospective research projects and data projects. We would therefore like to remind researchers of the applicable procedure.

As an academic hospital affiliated with KU Leuven, UZ Leuven has a legal and societal responsibility to advance healthcare, scientific research, and education, and conduct scientific research in public interest. The processing of personal data for retrospective scientific research may therefore rely on Article 6(1)(e) GDPR (task carried out in the public interest), subject to the applicable legal framework and appropriate safeguards.

When personal data are re-used for a new research purpose, the GDPR transparency obligations must be considered. This also applies where personal data originates from a previous study for which the data subject provided consent through an informed consent form. Such consent is not regarded as fulfilling the information obligation for each future research project individually. Where personal data are further processed for a specific new research project, patients must be appropriately informed about the purpose, nature, and design of this secondary use of their data.

To facilitate both the required privacy assessment and compliance with the transparency obligations towards patients, all research projects involving the processing of personal data must be submitted to EC together with a completed GDPR questionnaire.

At UZ Leuven, patient information can be provided efficiently through Mynexuzhealth. Information entered in the "Research" section of the GDPR questionnaire will automatically be transferred to Mynexuzhealth and serves to inform patients about the purpose of the research in which their data are being used. For studies requiring patient information:

- Patients should be flagged in KWS using the relevant study number (S-number).
- Information entered through the GDPR questionnaire, containing this S-number, is automatically linked to the patient and becomes available through Mynexuzhealth.
- For large study populations, the KWS Helpdesk can assist with bulk flagging when required.

This process offers a practical mechanism to support transparency towards patients while limiting the administrative burden for research teams.

We also refer to: https://wiki.uz.kuleuven.ac.be/display/KWShelp/Klinische+studies.

Overview of the Fees

Submission fees to EC apply to commercial studies, while these do not apply to academic studies. Part of the fees is legally established in the Royal Decree of 15 July 2004. We refer to the Federal Agency for Medicines and Health Products (FAMHP) for these fees.
In addition to the legally established fees, there are also submission fees for other types of study or study documents, as determined by EC Research UZ Leuven. You can find the agreed fees for these in the table below. These fees will be regularly adapted.

Type of Study	Amount	
	Initial	Amendment
Commercial studies not covered by the Experiments Act of May 7, 2004 (e.g., retrospective studies, MLM studies, other submission to EC…)	€ 1000	€ 500
Biobank recognition and biannual evaluation	€ 2000	
Non-study specific recruitment materials	€ 500	

Please provide the following information upon submission. Payment is only possible after receipt of an invoice from the financial department:

- Invoice address (preferably an address in Belgium)
- Name of the contact person
- PO number (Purchase Order), if applicable
- VAT number

Human genetic and genomic data: submission through EGA required (not RDR)

Please note that human genetic and genomic data should not be deposited in the KU Leuven Research Data Repository (RDR). Such data must be submitted to the European Genome-phenome Archive (EGA) and the applicable submission procedure must be followed. Researchers are required to consult and notify the Data Access Committee (DAC) prior to any EGA submission. Therefore, the application form should be submitted. For more information, we refer to: https://www.uzleuven.be/en/dac.

Population Screening Research in Flanders

Researchers involved in health-related or preventive research should be aware that population screening activities performed within scientific research may, in some cases, fall under the Flemish legislation on population screening. When applicable, review by the Flemish Working Group on Population Screening and a ministerial decision may be required. As this process can take several months, researchers are encouraged to assess the applicability of the legislation early during study planning. More information is available via Bevolkingsonderzoek Vlaanderen.

Distribution of Approval Letters

We would like to remind investigators that approval letters are sent by the EC to the contact persons they designated during the study submission process. These contact persons are responsible for further distributing the approval letter and any related correspondence, where necessary, to all relevant members of the study team, participating sites, sponsors, and collaborators as appropriate. EC does not distribute approval letters beyond the registered contact persons.

New Article on Research Ethics and Deception

Former EC member Dr. Kamiel Verbeke recently co-authored an article exploring the ethical challenges of conducting research that involves deception of participants. The authors propose a relational research ethics model that helps researchers navigate ethical decision-making during participant interactions while remaining aligned with ethics committee approval. The framework is built around five key principles: attunement to participants, being as truthful as possible, limiting harms and wrongs, diligent safeguarding, and promoting equality throughout the research process. Read the full article here: https://onlinelibrary.wiley.com/doi/10.1111/bioe.70178.UElkutm_medium=ios_app&rcm=ACoAAAueloYBIuMTEgk-4HhJ0liJ8T_5q1ljuZ4&utm_source=social_share_send&utm_campaign=mail

What You Need to Know About ICH GCP E6(R3) Annex 2

Annex 2 of ICH GCP E6(R3) (adopted on 3 June 2026) provides additional guidance for the Investigator and Sponsor for the planning, conduct, and oversight of clinical trials that incorporate evolving trial methodologies, such as decentralized trial elements, pragmatic study designs, and the use of real-world data. It complements the GCP Principles and Annex 1 by addressing specific considerations associated with these approaches, while continuing to safeguard participant rights, safety, well-being, and data reliability.
As clinical research continues to evolve, Annex 2 supports the application of GCP in a proportionate and risk-based manner, ensuring that innovative trial designs and data sources remain fit for purpose and compliant with regulatory expectations. It does not replace existing GCP requirements but should be read alongside the GCP Principles and Annex 1.

Considerations included in Annex 2 may be applied to evolving methodologies in clinical research provided they are implemented in accordance with local regulatory requirements.
Whether you have already completed GCP E6(R3) training or are preparing to undertake GCP training, it is important to be aware of Annex 2 and understand its relevance to clinical research.
Annex 2 is available at the ICH website: E6(R3) Good Clinical Practice (GCP) Annex 2

