Newsletter

Ethics Committee Research
UZ/KU Leuven

Number 31 - December 2025

Dear all,

At EC Research, our mission remains clear: to protect the rights, dignity, and well-being of all participants involved in clinical research while supporting you throughout your research journey. As an independent advisory body, we stand by your side to ensure every step is guided by ethics, safety, and respect.
We wish you a merry Christmas, joyful holiday season and a new year filled with health, happiness, and inspiring discoveries. May 2026 bring continued collaboration and success in advancing research that truly matters.

Warm regards,
EC Research

Members: Dominique Bullens, Ariel Alonso Abad, Pascal Borry, Francesca Bosisio, Guy Bosmans, Simon Brumagne, Catherine Cassiman, Valerie Christens, Ellen Deleus, Jean-Jacques Derèze, Erwin Dreesen, Lut De Groote, Theresia De Fraye, Jan de Hoon, Aernout De Raemaeker, Lia De Wilde, Dorien Fierens, Marie Gilliot, Rik Gosselink, Kelly Hoogeveen, Walter Janssens, André Loeckx, Koen Luyckx, Frederik Nevens, Marleen Renard, Peter Sinnaeve, Karin Sipido, Anne Smits, Mathijs Swaak, Anne Uyttebroeck, Marilien Vandeputte, Veerle Vanparys, Frank van Calenbergh, Ben Van Calster, Bart Van der Schueren, Laura Van Gerven, Kristel Van Landuyt, Katelijne Van Overwalle, Kristin Verbeke, Gregor Verhoef, Minne Casteels
Staff: Irene Borginon, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Kaat Van huyck, Indra Verhaeghe, Sofie Vervoort

Members EC Research

We say goodbye to professor Jan Verhaegen and professor Miet Schetz and thank both for their years of dedication to EC Research. We welcome dr. Sien Ombelet, dr. Melissa Depypere, dr. Heleen Marynissen and mr. Maarten Ganne.

Case report with transfer of (personal) data

When data from UZ Leuven are transferred to another center in the context of a case report, a data transfer agreement is not always required. The transfer is covered by the approval letter of EC Research, which specifies the conditions for the transfer. The transfer can take place, on the conditions
(1) that the data will be processed with appropriate care in accordance with the GDPR-principles,
(2) that the necessary measures are in place to allow for a secure processing preserving strict confidentiality of the data,
(3) that the data are only used for the specific purpose as submitted to EC Research, and
(4) that the data must be deleted by the receiving party or, where applicable, returned to UZ Leuven, upon completion of the project.

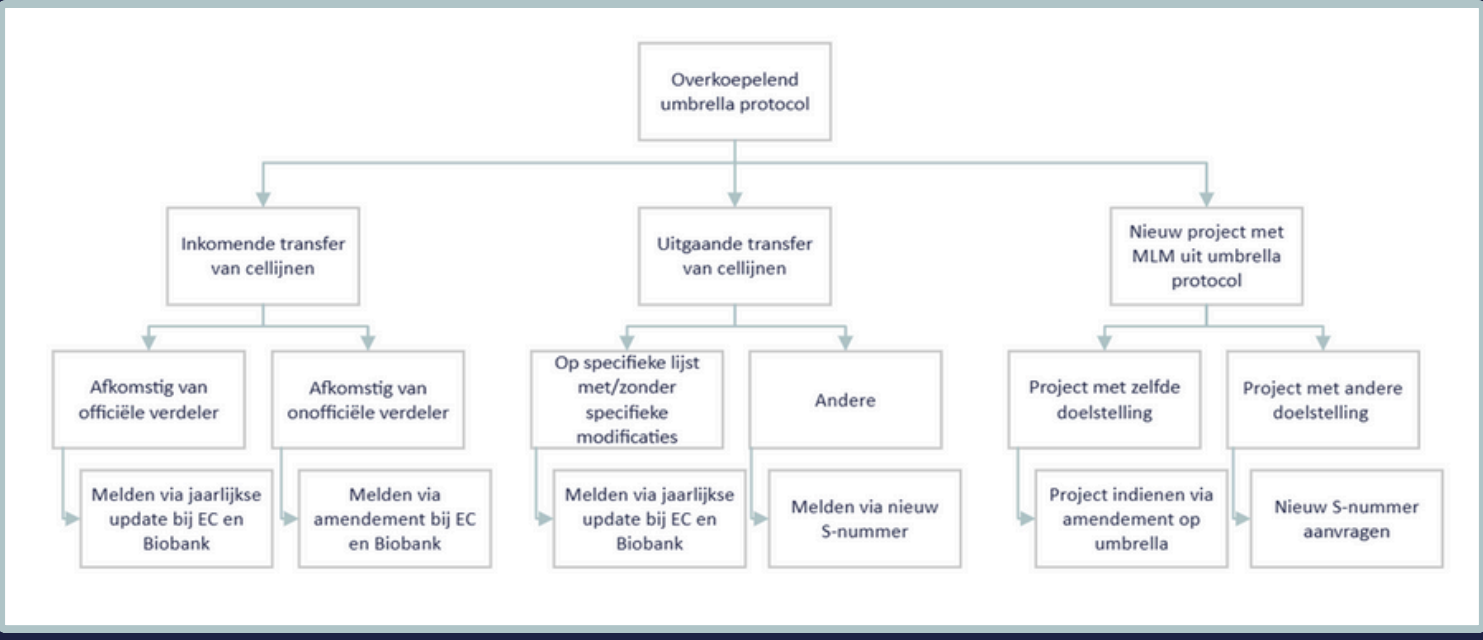
ICH-GCP (R3)

Since 23 July 2025, the new version (Revision 3) of the Good Clinical Practice guideline has entered into force. You can consult the new version via the following link: https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline. ICH E6(R3) introduces innovative provisions designed to apply across various types and settings of clinical trials, ensuring continued relevance in the face of ongoing technological and methodological advancements. This guideline provides a new language to facilitate innovations in clinical trial design, technology, and operational approaches. It encourages a risk-based and proportionate approach to conducting clinical trials, promoting fit-for-purpose solutions. It fosters transparency through clinical trial registration and result reporting and offers additional guidance to enhance the informed consent process.
The CT-College and FAMHP published an advice to sponsors and sites of clinical studies on the need for an updated ICH-GCP certificate for new submissions after the implementation of ICH-GCP (R3) on 23/07/2025. You can access it via the following link: https://consultativebodies.health.belgium.be/en/documents/advice-college-and-famhp-sponsors-and-sites-clinical-studies-need-updated-ich-gcp.
We are currently awaiting the updated training module from the seven Clinical Trial Centres (CTCs) in Belgium. This revised training will be made available via intranet (leercentrum).
Via the website https://globalhealthtrainingcentre.tghn.org/ich-gcp-r3/, you can also access a high-quality online course on ICH-GCP (R3). Upon successful completion, you will receive a recognized certificate. From 01/01/2026 CVs and/or GCP training certificates will need to refer to ICH-GCP (R3) training. Please also indicate the date of your last GCP certificate.

Flowchart research with artificial or extracted material

There are still misunderstandings regarding the required administration and registration to Biobank/CTC/EC for scientific research without medical application in humans, conducted with artificial or extracted material. For this reason, UZ and KU Leuven have prepared a document explaining the context, approach, and the administrative simplifications introduced by UZ and KU Leuven.
UZ and KU Leuven provide a clear framework and practical guidance, including when an exception regime with administrative simplification may be applied. An overview is provided below.

You can also find this overview on the website of EC Research: https://www.uzleuven.be/en/ethics-committee-research/guidelines-notes-and-training.



Use of external platform for recruitment

External companies such as Ionis Call Center, TrialTech, Tricals, and Clariness support participant recruitment through digital channels like social media. Interested individuals can contact them for information, during which personal details may be collected for initial prescreening. Eligible candidates are then referred to research sites or their contact information is shared directly with those sites.
While the use of such call centers may provide certain advantages in terms of accessibility and workload management, UZ Leuven is concerned about the broader implications of this approach. The use of recruitment platforms raises several important issues that warrant attention. Key concerns include privacy, patient perception whereby the treating physician is bypassed, and trust, and training and language barriers. UZ Leuven strongly advises against the use of external companies for patient recruitment. The note can be consulted on our website via the following link: https://www.uzleuven.be/en/ethics-committee-research/guidelines-notes-and-training.

When to inform and/or obtain consent for data collection

It is essential to ensure that participants are adequately informed about the collection and use of their data in the context of research. Please find an overview at the end of this letter.
This diagram illustrates when and how participants must be informed about data collection, as well as the situations in which explicit consent is required. Should you have questions regarding the application of these principles in your specific research context, please do not hesitate to contact EC.

Submission of a notification

Amendments that do not introduce any substantial changes in content must be submitted for notification to EC Research. When submitting a notification, we request that the principal investigator of the study be copied (cc) on the submission. In such cases, a signed cover letter is not required.

Question about the status of a submitted study

If you have any questions about the progress of your study or dossier, please do not hesitate to contact EC Research via ec@uzleuven.be. We can assess which steps are required to facilitate the process and ensure smooth progression.

Research participants at UZ Leuven – Privacy statement

Research may use existing patient data (retrospective) or involve the collection of new data (prospective), sometimes combined with biological samples such as blood or tissue.
UZ Leuven is strongly committed to protecting privacy in all research activities. A dedicated privacy statement outlines how data are used in research and what rights patients have when data are used for scientific research. You can read the full privacy statement: https://www.uzleuven.be/nl/privacy-en-uw-dossier/privacyreglement/u-neemt-deel-aan-onderzoek. Patients can be actively referred to this website for more information.

Explore the Clinical Trials Map

The Clinical Trials Map, developed by the European Commission and EMA, offers a visual overview of ongoing clinical trials in Europe. While it exclusively displays clinical trials, it partially addresses the growing demand from researchers and patients for greater transparency regarding study locations. Users can filter trials by geographic location or search for a specific trial and navigate to the participating sites. You can access the map via the following link: https://euclinicaltrials.eu/search-for-clinical-trials/trial-map/?lang=en.

Use of podcasts for participant recruitment

Although EC Research does not actively recommend the use of podcasts for participant recruitment, researchers may choose to use a podcast as a recruitment tool for study participants. In such cases, researchers are advised to consider two possible approaches:

1. Submit the full podcast script to EC for review before recording and publication.
2. Submit the podcast itself (draft only).

Please note that submitting a recorded podcast may lead to additional comments or ethical concerns.
Only after receiving EC-approval the podcast may be recorded and published online. It is not permitted to submit a podcast that has already been published. This ensures that all recruitment materials meet ethical standards before dissemination.

Update to DAC application form – Situation 1 (KU Leuven researchers uploading data to EGA)

The DAC application form for situation 1 has been updated. Situation 1 applies when KU Leuven researchers upload genomic data to the European Genome-phenome Archive (EGA). KU Leuven requires that participants in research projects are informed about the use of their genomic data for future research and the broad sharing of these data for secondary research purposes. The informed consent form (ICF) must explicitly allow for data sharing via controlled-access repositories—meaning the data will only be made available under specific conditions. Researchers must now indicate in the DAC application form where this information can be found in the ICF. Specifically, they are required to reference the exact paragraph in the ICF that addresses controlled-access data sharing.

To inform participants appropriately, the following text may be included in the ICF:

"Merk ook op dat gevoelige data zoals specifieke moleculaire en klinische gegevens (gegenereerd in de studie of bij niet nader bepaald onderzoek in de toekomst) op een strikt beveiligde en gecontroleerde, via het internet toegankelijke database (bv. het European Genome-phenome Archive, een archief voor genetische en fenotypische informatie van genetische studies) kunnen beschikbaar worden gemaakt. Dit kan gebeuren bij het delen van gegevens bv. in het kader van deelname aan internationale samenwerkingsprojecten of voor publicatiedoeleinden. Privacy beschermende maatregelen zullen in acht genomen worden (maar genetische sequenties zijn wel steeds uniek). De toegang tot deze gegevens kan ter beschikking gesteld worden van iedereen die een speciale aanvraag doet en die de voorschriften van het toegangsbeleid voor gegevens volgt (specifiek voor elke database). Deze aanvragen worden behandeld door een specifiek toegangscomité. Dit comité verbindt zich ertoe de regels inzake bescherming van persoonsgegevens (GDPR / AVG) na te leven."

Use of correct ICF Templates when UZ Leuven is the sponsor

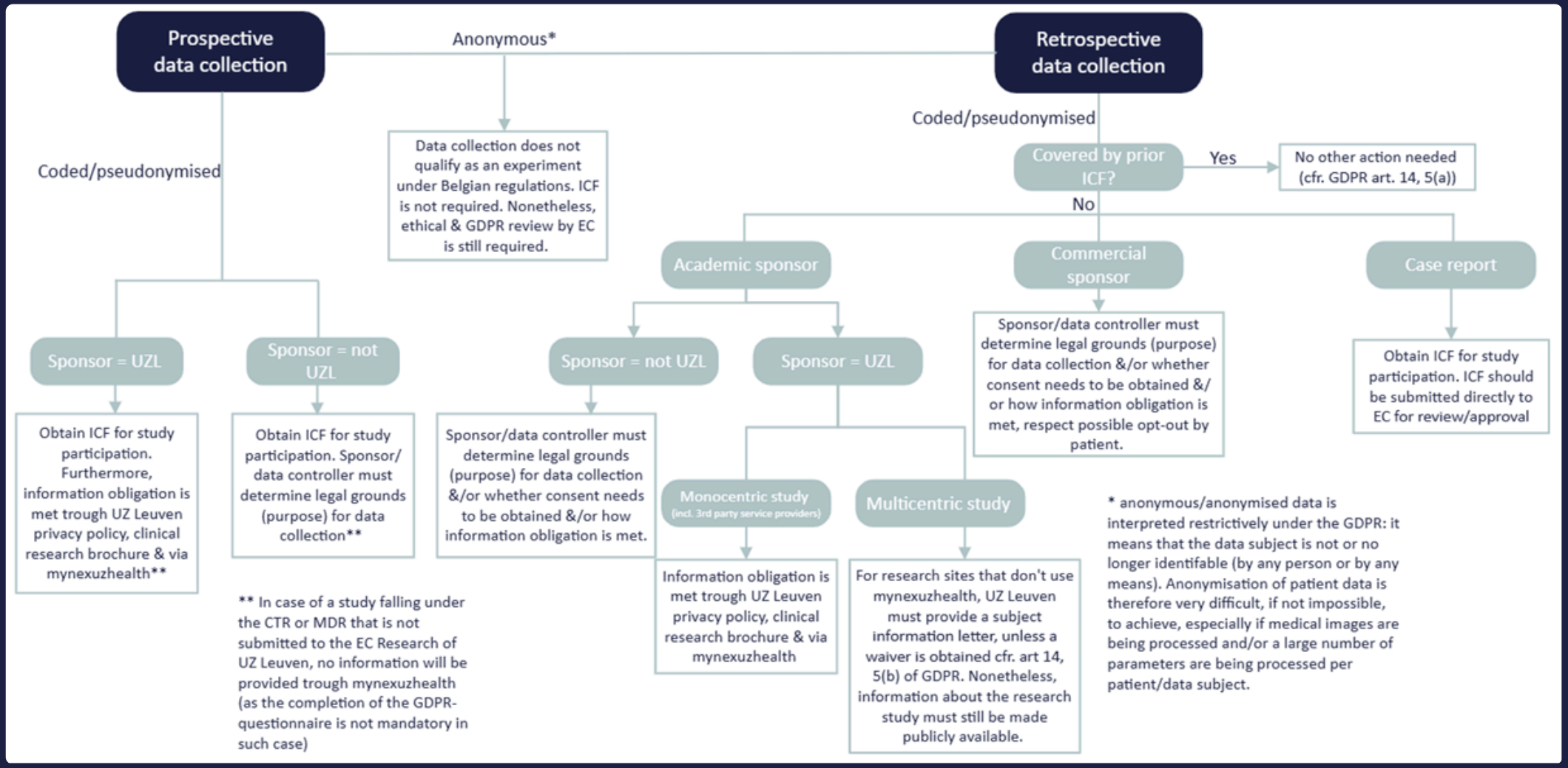
We would like to reiterate the importance of using the appropriate ICF templates when preparing a submission to EC. On our website, you will find several ICF templates, including specific versions to be used when UZ Leuven is the sponsor of the study.

You can access the templates via the following link:

https://www.uzleuven.be/nl/ethische-commissie-onderzoek/templates-en-interne-richtlijnen-bij-starten-van-dossier-bij-ec-onderzoek/informed-consent-formulier-icf-opstellen-voor-ec-onderzoek

We kindly ask all investigators and study teams to verify that the correct template is selected before submission.

When to inform &/or obtain consent for data collection for research?



Here’s to a new year of collaboration – meet the faces behind the work!