Newsletter

Ethics Committee Research UZ/KU Leuven

Number 28 – December 2024

Dear All,

At EC Research, our primary mission is to protect study participants while guiding you through your research endeavors.
We are committed to safeguarding the well-being, safety, dignity, rights, and privacy of patients and healthy volunteers participating in clinical research. Our role as an independent advisory body ensures that participant welfare remains our top priority.

Wishing you all the best in your research initiatives.

Sincerely,
EC Research

Members: Dominique Bullens, Ariel Alonso Abad, Pascal Borry, Francesca Bosisio, Guy Bosmans, Xavier Bossuyt, 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, Walter Janssens, André Loeckx, Koen Luyckx, Frederik Nevens, Marleen Renard, Miet Schetz, Peter Sinnaeve, Karin Sipido, Anne Smits, Mathijs Swaak, Anne Uyttebroeck, Annick Vanclooster, Marilien Vandeputte, Veerle Vanparys, Frank van Calenbergh, Ben Van Calster, Bart Van der Schueren, Laura Van Gerven, Kristel Van Landuyt, Katelijne Van Overwalle, Kamiel Verbeke, Kristin Verbeke, Jan Verhaegen, Gregor Verhoef, Minne Casteels.

Staff: Irene Borginon, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Kaat Van huyck, Indra Verhaeghe, Sofie Vervoort

Contacting study participants by phone

When contacting participants by phone as part of a study, it is crucial to clearly communicate who is calling and what the purpose of the call is. Be sure to introduce yourself with your name and role, and specify that you are a member of the study team. Additionally, explain that the call is pertains to the study in which the participant is enrolled.

Whenever possible, participants should be contacted by a member of the study team they have previously met during earlier study visits. This approach fosters trust and ensures a sense of continuity. To provide further context, mention the participant's treating physician and UZ Leuven during the call.

Registration form: "other submission" of projects to the EC

We would like to clarify regarding the "Other Submission" category mentioned in the registration form. This category applies to projects that do not involve:

- Experiments
- Clinical trials with medication (CTR)
- Clinical investigations with medical device (MDR)
- Performance studies (IVDR)
- Retrospective research
- Case reports
- The use of human biological material (whether primary or secondary use)

For these types of projects, approval from EC Research is not required. Examples include quality improvement initiatives, surveys related to internal organizational processes, surveys outside the healthcare domain, and focus groups with experts.

However, please be aware that many journals require IRB/EC approval anyway, regardless of legal necessity. If you plan to publish your study, submission for EC approval is highly recommended, as retroactive approval cannot be granted.

Even in the absence of a legal ground or if not required by UZ Leuven policy, you can still submit your project for EC approval. Please include at least a cover letter, your CV, and a project protocol. If additional documents, such as an Informed Consent Form (ICF) or questionnaires, are used, we kindly ask that you include these as well.

Please note that while submission is optional for projects under the "other submission" category, formal approval must be obtained before starting the project if you choose to submit.

Additionally, projects conducted exclusively at foreign sites, with UZ/KU Leuven as the sponsor, must also be submitted under this category. These studies are subject to local legislation and are required to be submitted to avoid issues such as ethics dumping.

Annual progress report

For studies subject to the Law of May 7, 2004, we kindly request you to submit an annual progress report. Submitting this report to the Ethics Committee in accordance with ICH-GCP guidelines is mandatory following ethical approval. The progress report serves as an extension of the EC's approval, and in the absence of this report, the study may be legally terminated.

We have noticed some confusion regarding the completion of the table in Section 2, 'Progress since study start' in the template available on our website: https://www.uzleuven.be/nl/ethische-commissie-onderzoek/goedgekeurde-studie-ec-onderzoek-aanvullen/vorderingsrapport-indienen-bij-ec-onderzoek.

- **Planned**: enter the **total** number of participants intended to be included in the study, as stated in the protocol. This is the sample size stated in the protocol and is not limited to the number planned for inclusion over a single year.
- **Screened and Enrolled**: provide the **cumulative** total number of participants since the start of the study, rather than figures for a specific year.
- **Deceased**: indicate the number of participants who passed away during **specific year**, as indicated by the reference 'since the previous APR' in the report.

We appreciate your attention to these guidelines to ensure the accurate and consistent submission of annual progress reports.

Submission of a case report

A case report is a detailed description of the diagnosis, treatment, and/or follow-up of an individual, exceptional patient. It typically includes demographic information about the patient (e.g., age, gender, and ethnicity).

Case reports can be submitted directly to the EC via the registration form without the need for submission to the CTC.

If data from a case report are shared with another center to compile a description involving multiple patients, a Data Transfer Agreement (DTA) must be used. Please use the template available on our website for this purpose: https://www.uzleuven.be/en/nl/ethische-commissie-onderzoek/case-report.

Inviting the Principal Investigator to Ethics Committee meetings for CTR Studies

Ethics Committees were recently instructed to invite the Principal Investigator (PI) of a CTR study to their meetings. This provides an opportunity for the PI to present the study, address questions, and clarify potential uncertainties. In most cases this will probably be an online meeting.
If you, as a PI, are unable to attend a meeting, please inform the (external) EC in a timely manner. This will allow the committee to invite an alternate investigator or study representative ensuring a productive discussion can still proceed.

Save the date: DAC Seminar

We are thrilled to announce the upcoming DAC Seminar, which will take place on **Friday, February 28, 2025**, from **12:00 to (at the latest) 15:30**. This seminar, organized by the Data Access Committee (DAC), will provide valuable insights into key aspects of data sharing and access for researchers.

I.a. Mahsa Shabani, Associate Professor in Health Privacy Law and Innovation at University of Amsterdam (UvA) will give a talk.

Additionally, we will provide an overview of the activities and processes of the DAC, including how researchers can submit their data to the European Genome-phenome Archive (EGA). We will also discuss the procedure for handling requests from external researchers who wish to access existing datasets and explain how you, as a researcher, can request access to external datasets yourself.

Mark your calendars and stay tuned for further details. Don’t miss this opportunity to learn more about data access processes and best practices!

Note: Accreditation for M.D.’s will be applied for.

Winter clock stop

Please be informed that EC Research will be closed from 23rd December till 2nd January 2025.
All submissions in this period will receive 2nd January as submission date.
Wishing you a merry Christmas and a happy New Year!

Costs for Foreign Patients in Clinical Studies at UZ Leuven

Foreign participants in clinical studies at UZ Leuven must be informed that they are not covered by the Belgian social security system. Similar to standard exams or treatments provided as part of routine care in Belgium, foreign participants are required to cover the costs of any standard care conducted within the study, as they do not have access to health insurance in Belgium.

However, study-specific procedures will be covered by the study budget and will not incur any charges for the participant.

The Informed Consent Form (ICF) specifies:
"As described in paragraph 4, the examinations and treatments specifically related to the study will not be charged to you. However, the treatments and examinations that are part of the standard care for your condition will be charged to you or your health insurance provider."

For foreign participants without Belgian social security coverage, it is critical to emphasize that the phrase "charged to you" applies, rather than "charged to your health insurance provider." This distinction should be clearly communicated during the ICF interview to ensure full understanding and allows participants to make an informed decision about their participation. We would like to request that appropriate attention be given to this matter during the explanation of the ICF to these foreign patients.