Newsletter
Ethics Committee Research UZ/KU Leuven
Number 27 – November 2024

Dear all,

As EC Research we have the task to protect study participants and to guide you through your research endeavours.

Our ongoing mission is to contribute to safeguarding the general well-being, safety, dignity, rights, and privacy of patients/healthy volunteers participating in clinical research. EC ensures independent advisory services, always prioritizing the welfare of the participants.

We wish you all the best in your research iniriatives.

Ethics Committee Research UZ/KU Leuven

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1. Clinical Research Office

Investigators and study teams are invited to proactively schedule a consultation with the Clinical Research Office on specific questions and challenging or innovative aspects of a planned clinical research project. The Clinical Research Office initiative is meant to promote project quality, increase project success rate and facilitate smooth study start-up through collaborative sharing of knowledge, expertise and best practice.
You can schedule an appointment to obtain project-specific answers and guidance with regards to study start-up, legal matters, complex partnerships, data (sample) management, monitoring, safety reporting, cost estimates, etc. During the Clinical Research Office the subject matter experts of the Clinical Trial Center, the Ethics Committee Research and the Biobank are present to answer your question(s).
When: 1st Tuesday (1-3:30 PM) and the 3rd Friday (10-1PM) of each month
Where: Consultations are held online via Microsoft Teams.

How:

- First have **a look** at the **websites** of the Clinical Trial Center, Ethics Committee Research and Biobank.
- Schedule an appointment by selecting a time slot and submit your question(s).
- **Be specific when formulating your question,** in order to select the right experts to be available at the requested time slot.
- For **studies that have already an S-number**, please check the status in PeopleSoft and contact the person that is assigned to your file directly, **not the Clinical Research Office**!
- **Be well prepared** when coming to the Clinical Research Office.
- For PhD students we request the presence of their promoter.

2. CTIS Helpdesk for non-commercial sponsors

The Accelerating clinical trials in the EU (ACT EU) initiative has established a dedicated helpdesk, which employs different measures to support non-commercial sponsors in navigating through the clinical trial landscape in the EU. Currently, the helpdesk offers tailored technical assistance on CTIS functionalities and addresses questions on regulatory requirements related to the clinical trial lifecycle. The helpdesk may also consult National Competent Authorities to provide support on specific cases.

Non-commercial sponsors can submit their question now by raising a ticket in the CTIS Service Desk and indicating their status as a non-commercial sponsor in the mandatory field “User affiliation”.
Link to CTIS Service Desk

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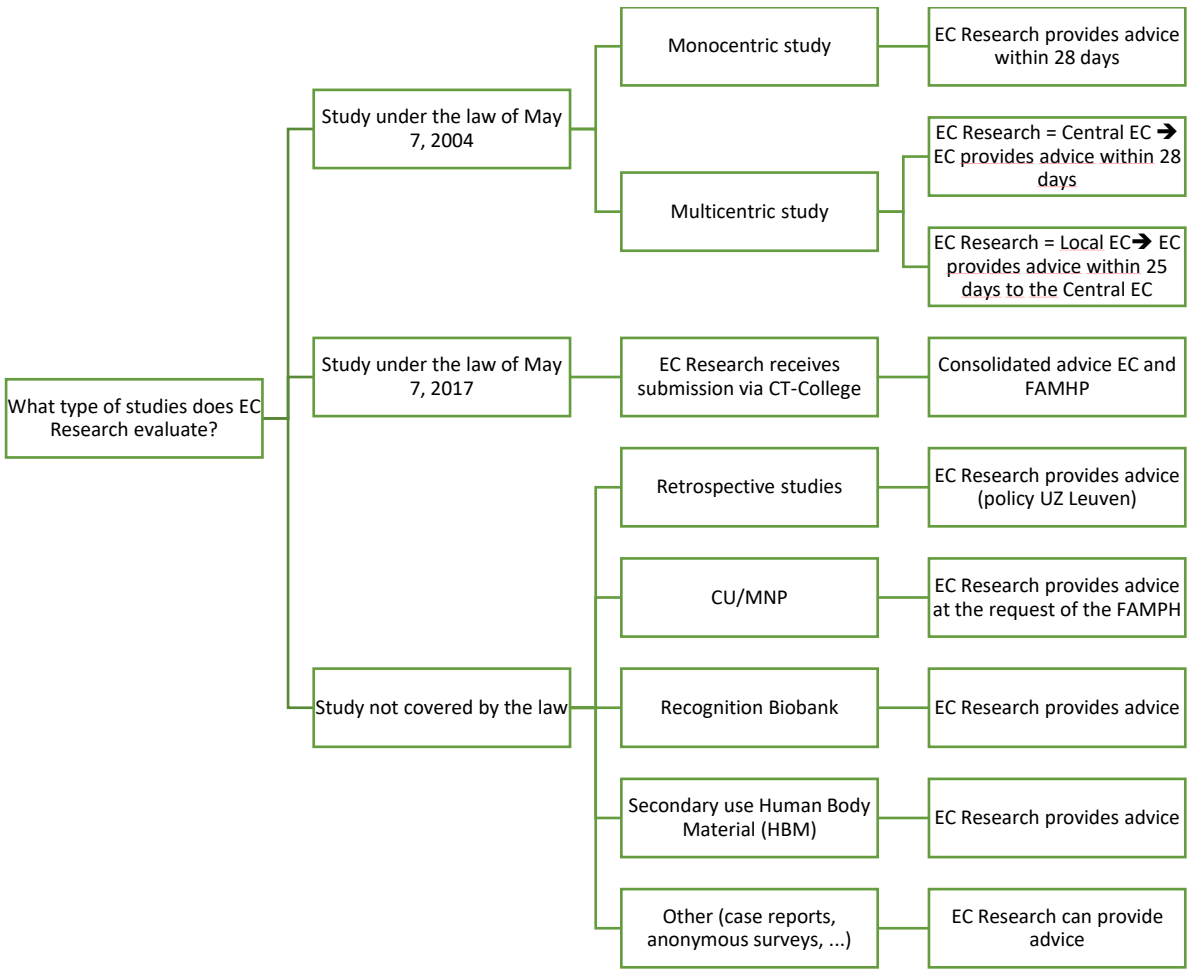
3. Which studies does EC Research evaluate?



About the category “other”:

Researchers sometimes ask us whether their study can also be submitted to the SMEC (Social and Societal Ethics Committee).
SMEC is authorised to evaluate research proposals involving human participants insofar as i) these proposals do not fall under the Human Subject Experiments Act (i.e., the "Experiments Act" of May 7, 2004), ii) there is no involvement of UZ Leuven patients (data) and/or staff, and iii) the studies do not take place on the campus of UZ Leuven. In addition, it is advised to submit all study proposals within the (bio)medical research area to EC Research. A decision tree has been established to help researchers at KU Leuven submit research projects to the appropriate ethics committee (EC) using a decision tree; https://www.uzleuven.be/en/ethics-committee-research/smec. A number of recommendations are made to assist researchers in their choice and give them an understanding of how the regulatory framework for ECs works.

4. Change of contact information during the study

If contact information changes during the course of a study, it is important to promptly report these changes to EC. This ensures that all communication can proceed accurately and on time, allowing the study to continue without interruptions.

5. Clarification on Master's Thesis integration with approved projects

All master's theses within the Biomedical Science Group must undergo an ethical review procedure. Every student needs to fill in a questionnaire in order to determine **what type of approval is required for their research project** . One of these questions is: "The research in the master's thesis is an integral part of a project that has already been approved by an authorized ethics committee."

It has come to our attention that while these theses utilize data collected from previously approved projects, they often present distinct research questions that warrant separate consideration.
This raises a critical question about the meaning of "integral part." When a project addresses a unique research question, it cannot be deemed as an integral part of an existing approved study. In such instances, amendments to the original project (to be submitted to EC Research) **or the submission of a new application is required**, or a new application should be submitted for review.

We encourage all students to provide clarity in their research proposals and to adhere to the necessary procedures for ethics approval.

6. CV of the principal investigator

Medical research involving human participants must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Such research requires the supervision of a competent and appropriately qualified physician or other researcher (cf. Article 12 Declaration of Helsinki).

It is essential that all relevant information is included in the CV of the principal investigator to ensure it accurately represents his/her qualifications and experiences. On the website of the FAMHP, a CV template is available which has been developed by the European Commission, including a specific BE addendum to capture technical expertise requirements unique to Belgium:
https://www.fagg.be/nl/menselijk_gebruik/geneesmiddelen/geneesmiddelen/onderzoek_ontwikkeling/klinische_proeven/europese.
Although this template was initially designed for CTR studies (clinical trials involving medicinal products), it is versatile and suitable for use across all types of research studies. This comprehensive template ensures that researchers can provide a complete overview of their qualifications, including areas of specialized expertise, which can help streamline the ethics review and approval processes. We encourage all researchers to utilize this template.

7. Declaration of Helsinki version October 19, 2024

The World Medical Association (WMA) Declaration of Helsinki (DoH) on 'Ethical Principals Involving Human Participants', established in 1964, is a set of ethical guidelines for medical research involving human subjects.

While not legally binding, the DoH has influenced policies and regulations globally. ICH Good Clinical Practice (E6), the EU Clinical Trial Regulation and our own UZ Leuven protocol templates all refer, in one way or another, to the

principles that have their origin in the DoH. By signing the protocol signature page, the PI agrees to adhere to the principles outlined in the most recent version of the DoH.

On 16 October 2024 a new and substantially revised DoH was published. Here are some of the most significant changes in the 2024 revision:

- The term *"subjects"* has been replaced with *"participants"*
- Article 8 emphases the importance of upholding ethical standards even during public health crises.
- Article 12 is about the recognition of scientific integrity as fundamental in all research involving human participants and reinforcing accountability for researchers and the institutions they represent.
- New guidelines (Articles 19 and 20) address the importance of equitable access for vulnerable and marginalized groups in research. The revision calls for fair treatment and, when justified, the inclusion of individuals in vulnerable situations, with protections tailored to their needs. When possible, research should directly address the unique health needs of these populations to avoid perpetuating health disparities.
- The update calls for ethics committees overseeing research to have adequate resources, training, and independence from researchers or sponsors, ensuring their ability to properly evaluate and monitor research protocols without undue influence (Article 23).
- Updated guidelines on the use of personal and biological data in research, including long-term storage and secondary uses (Article 32).

For further details, the full declaration can be reviewed on the World Medical Association website: https://www.wma.net/policies-post/wma-declaration-of-helsinki/

8. Highlighting changes in amended documents

When submitting revised documents—whether in response to EC comments or as part of a modification—we kindly ask that all changes be clearly indicated within the amended documents. Ideally, these updates should be marked using *track changes*. This method allows us to see not only the added text but, more importantly, any deleted text as well.
Please note that highlighting changes with fluorescent colors alone is less effective, as it does not clearly show removed text. Using track changes will help expedite our review process by making all modifications immediately visible.