Newsletter
Ethics Committee Research UZ/KU Leuven
Number 14 – July 2021

Dear researchers and teams

With this newsletter we would like to assist you in doing high-quality clinical and translational research with respect for the well-being and privacy of each patient and volunteer.

We wish you a beautiful summer!

Ethics Committee Research UZ/KU Leuven

Members: Dominique Bullens, Ariel Alonso Abad, Pascal Borry, Guy Bosmans, Xavier Bossuyt, Simon Brumagne, Michèle Dekervel, Jean-Jacques Derèze, Erwin Dreesen, Lut De Groote, Theresia De Fraye, Jan de Hoon, Aernout De Raemaeker, Lia De Wilde, André Loeckx, Koen Luyckx, Ben Nemery, Marleen Renard, Angélique Rézer, Miet Schetz, Karin Sipido, Anne Smits, Mathijs Swaak, Josse Thomas, Anne Uyttebroeck, Annick Vanclooster, Liliane Vandergeeten, Marilien Vandeputte, Veerle Vanparys, Ben Van Calster, Kristel Van Landuyt, Katelijne van Overwalle, Jan Verhaegen, Gregor Verhoef, Minne Casteels

Staff: Stephanie Brams, Amber Bruijnes, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Indra Verhaeghe, Sofie Vervoort

1. Procedures for the use of bodies and body material in research

Researchers intending to conduct a study on bodies and/or body material have to submit an application. Different procedures exist for the use of a) bodies of deceased persons who have donated their bodies via their will, b) without will and for the use of body material of living donors.

a. Procedure for the use of a body/body material donated via a will

If you intend to conduct a study on post-mortem bodies/body material originating from deceased patients who indicated before their death via their will that they agree to certain body materials being used for research at KU Leuven, ethical advice must be obtained via EC Care. You must submit a request via EC Care, after consultation with the responsible persons of Anatomy.

This post-mortem material is never disease-specific.

When submitting the application, you should make it explicit that:

- it concerns bodies that have been donated to KU Leuven via a will for the benefit of science;
- the principle of 'bodies must be complete for the funeral', as required in the guidelines of Anatomy, is met. If it concerns a smaller quantity of tissue that cannot be attributed to an individual body, this must also be made explicit in the protocol.

b. Procedure for body material of living donors / deceased donors without a will

Other studies involving the use of human body material, whether derived from living donors or deceased donors who have not donated their bodies to science via will, must be submitted to EC Research for approval (cf. Law of 19 December 2008 and Law of 7 May 2004 on experiments), after validation by the Clinical Trial Center (CTC).

The same procedure applies to studies involving the 'secondary' use of residual human bodily material or studies that prospectively collect bodily material from living donors for research purposes.

2. Communication to co-investigators

In line with scientific integrity the PI involves the co-investigators and informs them appropriately. To underscore this involvement we will include (cc) the co-investigators in the communication with EC Research.

3. Acceptability of PI and facilities

As communicated in the past, from February 2022 another EC will evaluate your submitted EudraCT studies. This implies that the competence of the PI and the details about the facilities have to be sufficiently described, so please take care to document these properly.

4. Conflict of interest (COI)

In previous newsletters (April 2019, July 2020), we highlighted the importance of a good accompanying letter which highlights the essential elements of the study, and indicates in which parts the UZ/KU Leuven site will participate. We also invite you to highlight any potential conflicts of interest in this accompanying letter. It is the PI's responsibility to declare any potential COI.
A conflict of interest in research refers to situations in which financial or other personal considerations may compromise, or could lead to the perception of compromising a researcher's professional judgment in conducting or reporting research.

5. (Non-)substantial modifications

If the sponsor wishes to make substantial modifications to the protocol after the start of the study, the reasons for and details of these modifications must be submitted to EC Research in an amendment.

Modifications are considered **substantial** if they are expected to have a significant effect on:

- the safety or physical and psychological integrity of the participants in the clinical trial
- the scientific value of the trial.

It is up to the sponsor to assess whether a change is "substantial".

It is not obligatory to submit non-substantial amendments, although it is advisable to notify EC Research. These modifications should be documented anyway and be included in the submission at a later stage, e.g. with the subsequent submission of a substantial modification.

EC Research will send you a notification letter upon receipt of the non-substantial modification, but will no longer send an Acknowledgment of Receipt (AoR).

6. Studies in which employees are involved

EC Research often receives studies in which employees are approached as participants. They are invited to participate in interviews, to complete a questionnaire or survey,…
As decided by the executive committee UZ Leuven, this kind of studies requires the agreement of the executive committee of the corresponding company/organization.
More specifically, for UZ Leuven:

- For nursing staff of UZ Leuven you submit your request to the Director of nursing and the HR director;
- For medical staff or medical trainees (ASO) you submit your request to the Medical Director and the HR Director;
- For employees of UZ Leuven not belonging to nursing or medical staff, you submit your request to the HR Director.

EC Research just reminds you of this requirement – no proof of agreement should be provided to EC.

7. Phase I/II

For a Monocentric Phase 1 study the evaluating EC has only 15 days to provide its opinion. For a Phase 2 and Phase 3 this is 28 days.
For a Phase 1/2, FAGG indicates that 28 days are allowed.

8. Research quality

To find trustworthy answers to research questions, robust methodology plays a fundamental role from study planning to study reporting, as stated in this article by prof. B. Van Calster.

Failure to uphold methodological standards leads to genuine ethical problems. It is unethical to expose humans or animals to any risk or inconvenience by research that is methodologically unsound. All researchers should undertake efforts to improve medical science. Training in statistics and methodology should discuss how studies are designed, and how research questions are translated into study procedures, data collection processes, and analysis tools.

9. Proper pdf files

May we kindly invite you to only provide us with "searchable" pdf-documents, and not old school scanned papers, which make life for reviewers (very) difficult.

10. Interactions, contraception…

For early drug development the FAGG/FAMHP very often comments on insufficient information about food/drug interactions of the IMP, or insufficient/incorrect measures on contraception/fertility issues. We invite you to check these issues in your applications before submission, in order not to lose precious time.

info

ec@uzleuven.be
www.uzleuven.be/ethische-commissie/onderzoek
Telephone: 016 34 86 00 (between 10 am and 11 am)