UZ LEUVEN

Newsletter

Ethics Committee Research UZ/KU Leuven
Number 21 - July 2023

Dear researchers and team

We wish you all a happy summer!
With this newsletter we hope to support you in doing high-quality clinical and translational research with respect for the well-being and privacy of each patient and participant.
Ethics Committee Research UZ/KU Leuven

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1. Global Code of Conduct for Research in Resource-poor Settings

Ethics dumping describes the export of unethical research practices from higher-income to lower-income settings. Ethics dumping can take many forms. Sometimes it is willful exploitation: researchers avoid local ethics approval, undertake highly unethical experiments on non-human primates, refuse requests for compensation for harm incurred during a research study or do not offer a fair choice to a potential participant (no treatment or participating in a clinical trial). Conducting research abroad should be in line with what would also be ethically acceptable in the investigator's institution/country (i.e. KU/UZ Leuven/Belgium). Researchers should avoid engaging in projects or co-operations that bear a risk of ethics dumping, or should take measures to prevent this risk.
The European Commission has insisted since 2014 (the launch of Horizon 2020) that European ethics rules apply abroad. In 2018 the European Commission announced a crackdown on ethics dumping to make sure research practices deemed unethical in Europe are not exported to other parts of the world. The European Commission has adopted the **Global Code of Conduct for Research in Resource-Poor Settings** (GCC), which is used to serve as an educational tool for researchers and as a general ethical framework for scientific research in partnership with, or conducted in, lower- and middle-income countries. This accessible standard for ethical research can help academics make decisions based on the core principles of fairness, honesty, respect and care.

You can find more information about Ethics Dumping here: https://www.youtube.com/watch?v=tP_j0KXVskk, and you can find the code here: www.globalcodeofconduct.org/.

All projects involving human subjects that are planned or performed by UZ/KU Leuven staff in research institutes located outside the EU must be submitted for approval to the ethics committee of the host institute where the experiments take place, so local ethics review should be sought wherever possible. It is of vital importance that research projects are approved by a research ethics committee in the host country, wherever this exists, even if ethics approval has already been obtained in the high-income setting. Indeed, we also request a submission to EC Research, even when the study does not take place in Leuven/Belgium.

KU Leuven endorses the Global Code of Conduct for Research in Resource Poor Settings.

2. Optimize the study submission and approval flow

We are pleased to share some significant updates regarding the optimization of our study submission and approval process, initiated by a working group established in September 2021.

The motivation behind the start of this working group was to address the Biobank's policy plan for 2020-2025, which emphasized the importance of clear communication by the Biobank. Its primary objective was to establish distinct roles and responsibilities between the Biobank, the Clinical Trial Center (CTC), and the Ethics Committee (EC).

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The aim was to eliminate redundancy and streamline operations, ultimately reducing turnaround times. The working group, led by ir. Veerle De Ganseman, includes members from WBB/EC/CTC, along with researchers and LRD staff.

Currently, the CTC manages the initial review of studies. Upon validation, the study is then submitted to the EC. Additionally, if the study involves the processing of human body materials, approval from the Biobank is also required. However, researchers often find it challenging to discern which body reviews specific documents and who to approach for feedback at different stages of the process.

To address this issue, the working group proposes maintaining a unified “front door” for study submissions, although it will not necessarily be handled exclusively by the CTC desk. A new application form will be introduced, incorporating targeted questions that will guide researchers through a decision tree. Based on the responses, the system will determine the appropriate entity by which the study should be initially reviewed.

We believe that implementing this approach will streamline the submission process, reduce confusion, and enhance overall efficiency. We appreciate your ongoing support and collaboration as we work towards optimizing our procedures.

3. Annual report EC Research 2022

The Annual Report for the year 2022 of EC Research can be accessed at our website: https://www.uzleuven.be/en/ethics-committee-research/annual-report-ec.

The Annual Report provides a detailed overview of the progress over the past year. EC Research had 48 meetings in 2022, compared to 36 in 2021. A total of 1357 protocols were reviewed in 2022. In 2021, there were 1369. In addition, 1155 amendments were evaluated in 2022, compared to 1133 in 2021.

4. Standard Operating Procedures (SOP) in Muzlidoc

EC Research has revised and updated some of her procedures. You can find them on Muzlidoc: https://wiki.uz.kuleuven.ac.be/display/muzlidoc/EC+onderzoek.

The updates encompass various aspects, including the evaluation of research protocols, the protection of human subjects, the assessment of potential conflicts of interest, and the overall compliance with ethical guidelines and regulations.
Should you have any questions or require additional information regarding the recent updates to our EC procedures, please do not hesitate to reach out to us.

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5. Ethics and Privacy in Child and Youth Research

When dealing with minors in research, specific ethical and privacy related issues arise. On April 28th, a L-C&Y Methods Club was organized by the KU Leuven Child and Youth Institute about this topic. Together with Laurens Vangeel (SMEC), representatives of EC Research (with a special thank you to dr. Marleen Renard), gave a presentation discussing this.
You can find the recording here:
https://www.kuleuven.be/child-youth/en/methods-club/4-ethics-and-privacy/ethics-and-privacy-in-child-and-youth-research

6. Procedure for medicinal products in compassionate use and medical need programs, urgent situations, off label use, samples and import

In our newsletter of December 2022, we summarized the process to submit a compassionate use program and medical need program. Together with the legal departments of UZ Leuven and of the CTC, the pharmacy and EC Research, a more detailed procedure and a flow chart were conceived with input from clinical staff and CTA's. This procedure describes the possibilities described in Belgian legislation for the administration of medicines in compassionate use programs ("CUP"), medical need programs ("MNP"), urgent situations, off label use, samples and import with respect for the therapeutic freedom of the physician. The prescription of medicinal products within UZ Leuven always takes place at the initiative and under the responsibility of the treating physician, a staff member (vms). The treating physician bears the final responsibility with regard to treatment of and administration to the patient.

The procedure will soon be available in Muzlidoc.

7. Clinical studies with questionnaires

The Belgian Association of Research Ethics Committees (BAREC) has given an advice on how to consider studies involving questionnaires (outside standard of care (SoC)) to be interventional or non-interventional, in case no additional diagnostic or monitoring procedures are proposed in these studies. Participants will only be requested to complete a questionnaire, and potentially, data can be collected from their medical records.
BAREC wants to highlight that questionnaire completion should not result in longer duration of consultation room occupancy, and should be done at a pre-specified, convenient location with the necessary comfort and privacy for the participant.

It is applicable to studies in which the questions are processed pseudonymously and which fall under the (Belgian) law of 7 May 2004.

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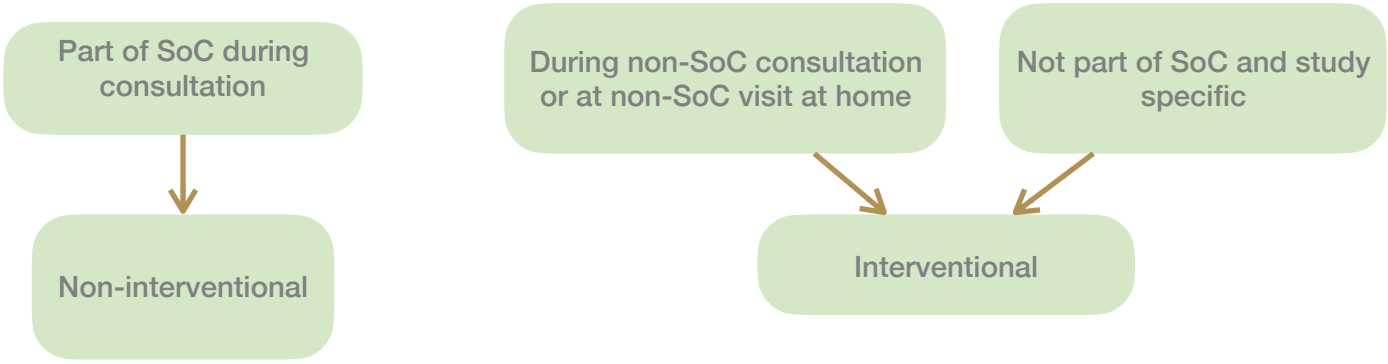
Please note that interventional studies with questionnaires that also investigate the safety or efficacy of one or more medicinal products, which all have a marketing authorization, are covered by the Clinical Trial Regulation (CTR) and therefore not by the (Belgian) law of 7 May 2004. We refer to the definition of a low-intervention clinical trial according to article 2 (2)(3) of the CTR.

Remember:
Anonymous questionnaires and quality improvement projects do not resort under the Law of 7 May 2004, but of course limitation of the consultation room occupancy, convenience and privacy of the participant are also important here.



However, EC may ad hoc decide that questionnaire study is considered non-interventional:
- based on content of questions
- if completion of questionnaire requires less than 30 minutes of participant's time
- if questionnaire becomes future part of SoC

8. Planning study-related investigations

For the organization/appointments of function measurements in a study context in UZ Leuven (for example requesting an ECG in a study setting), we would like to remind the following rules. Please always mention this information in the request:

1. The S number and name of the study.
2. If it concerns studies assigned to a specific person (e.g. echocardiographer): please ascertain first (e.g. call) that the specific person in question is available for the dedicated study appointment.
3. For triplicate ECG or for specific measurements during the ECG: always mention this on the request (with possibly the duration in between).
4. If you give a form to be filled out by the patient: put it in an envelope with the name of the study nurse on it and duly inform the patient how the form will be returned.

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