Newsletter
Ethics Committee Research UZ/KU Leuven
Number 15 – October 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 participant.

Ethics Committee Research UZ/KU Leuven

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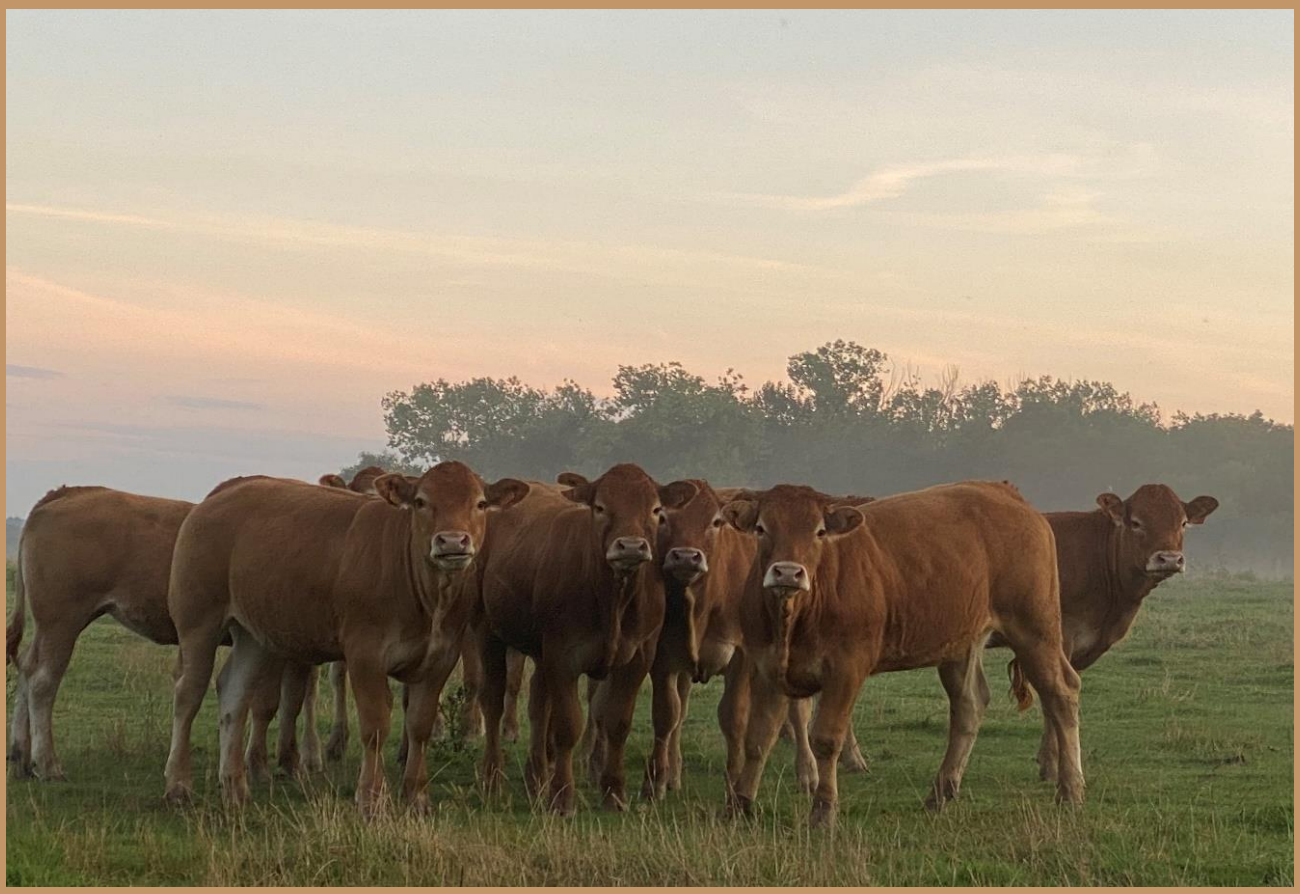


1. Template protocol retrospective studies

On the website of the Clinical Trial Center there is a link to a protocol template for a retrospective study when UZ Leuven is the sponsor. From **1st January 2022** it will be mandatory to use this template for submission of such studies to EC Research (or OBC).

2. Training information

The Ethics Committee has added the "**Training Information**" page on its website. This page will be regularly updated with interesting literature and other information/presentations. You will already find **a lecture on the use of REDCap**, explained by Hilde De Tollenaere (Clinical Trial Center, CTC) and a presentation **on pitfalls for clinical decision support based on Artificial Intelligence** (AI), explained by Prof. Ben Van Calster. It is definitely worth watching these trainings. Many thanks to both for making these lectures online available!

3. Signed cover letter Principal Investigator

We invite the principal investigators to pay extra attention to the cover letter that must be submitted to EC with each new study/substantial amendment. A good cover letter, with some brief, but clear information about the study, is very important.

The cover letter must be signed by the principal investigator but please note that when the PI is in cc of the submission (including commercial study submissions), he/she does not need to sign the cover letter anymore.

4. Invitation

If you, as a clinical staff member of UZ Leuven, would be interested in joining EC Research, you are welcome to contact the chair Minne Casteels (016330286 or minne.casteels@uzleuven.be). Being a member of EC Research offers you a privileged view on the university, its hospitals and its research(ers). You can apply as a duo (effective/alternate) in order to limit the workload and you can be member for 2 years or more.

5. Monocentric – multicentric???

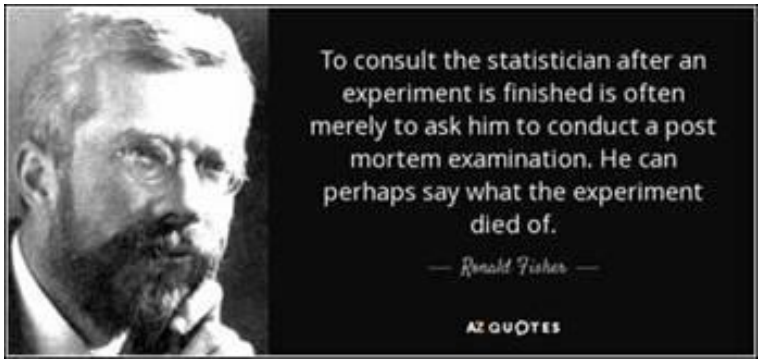
We often observe some confusion about this terminology. If multiple centers in Belgium are involved it is a multicentric study. If only 1 center in Belgium is involved (even with many international centers), as EC we evaluate this as a monocentric study, only for the Belgian center.
In the Belgian law of may 7, 2004 concerning experiments on the human person, article 2, a multicenter study is defined as follows:
"Een experiment dat volgens één bepaald protocol, maar op verschillende locaties en derhalve door meerdere onderzoekers wordt uitgevoerd."

When a study is conducted at different sites in Belgium, it is always important to check whether there is a researcher involved from the other site. For example, if the principal investigator of UZ/KU Leuven conducts the study himself at UZ/KU Leuven and at another site, then we consider this a monocentric study. In that case, only the approval of the EC of UZ Leuven and additionally the approval of the Board of the institution for the use of the facilities are needed.

6. Statistical Analysis Plan

EC would like to stress the importance of a scientifically valid protocol, including clear research questions and objectives, description of primary and secondary endpoints/outcome. A justification in the protocol of the number of participants (sample size) that will be included is essential. The statistical analysis plan should also contain the test/model used for the sample size calculation. It should also contain a description of any other analysis that will be carried out.

EC would like to direct you to the following website of the "Leuven Biostatistics and statistical Bioinformatics Centre (L-BioStat)": https://gbiomed.kuleuven.be/english/research/50000687/50000696. To all researchers of the Group Biomedical Sciences, L-BioStat offers consultation to provide statistical advice on various methodological and statistical aspects of the research project. Free advice is provided through scheduled one hour consulting appointments. Furthermore, it also offers in-depth collaborative consulting, including analysis of data, writing of a statistical report and incorporation of the results in (an) article(s). You can also discuss/collaborate with colleagues with extensive biostatistical expertise, from several departments in KU Leuven both in Biomedical Sciences as in the other groups.



7. Master's student access in KWS

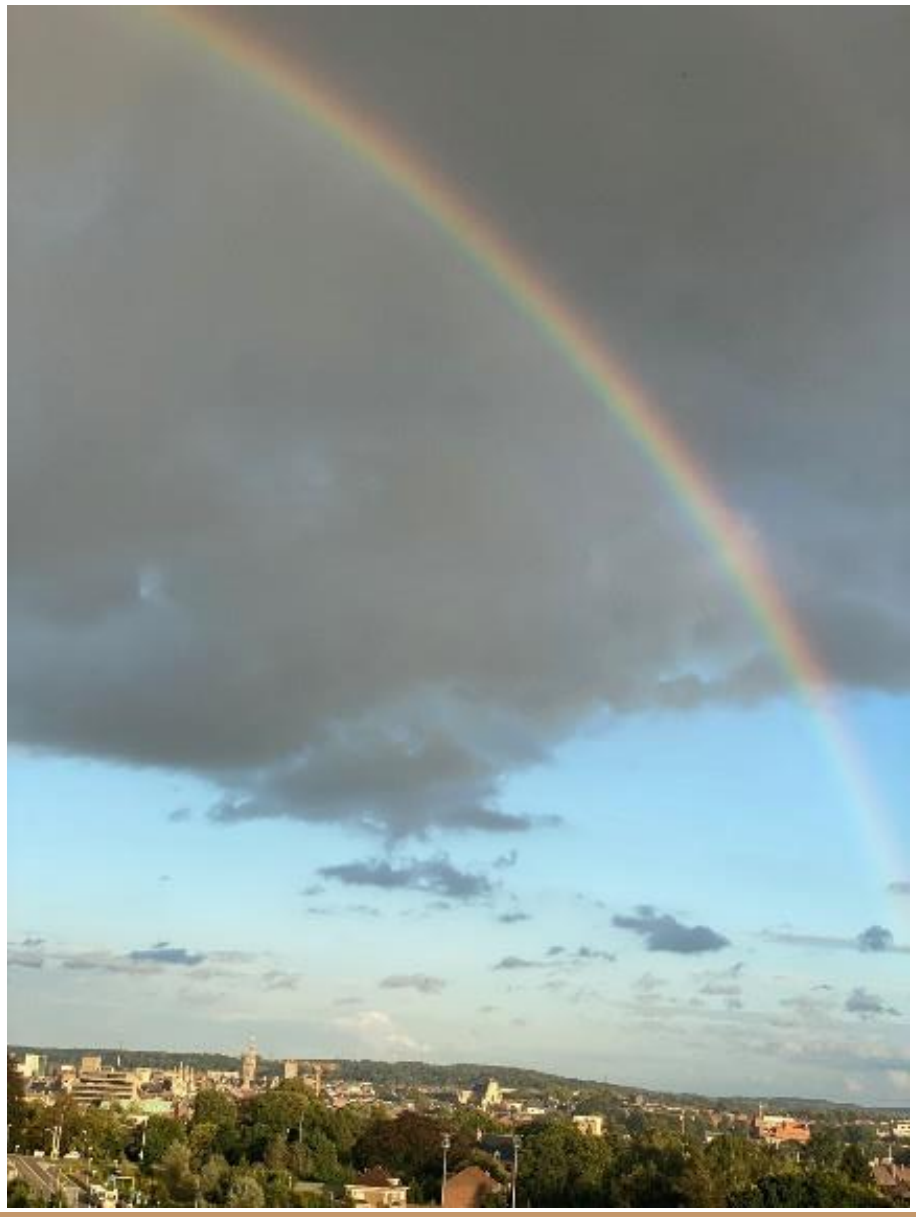
Access rights may be requested to the centrally managed systems in which health data are maintained such as KWS. A person can only get access to KWS if all of the following conditions are met:

- known in PeopleSoft HR;
- bound by professional or contractual confidentiality and the UZ Leuven duty of discretion, as well as being aware of the possible controls and sanctions for improper use of access rights;
- received training on privacy, data protection and discretion (i.a. GDPR and privacy for clinical researchers | UZ Leuven).

For students, a distinction is always made between a "qualified student" and another student. A student is a "qualified student" if, in addition to the basic requirements, he/she also meets the following two conditions:

- Being the holder of a Bachelor's degree

Being enrolled in a Master, Master-after-Master or Doctoral program in health care professions or BMW - majoring in clinical Biomedical Sciences qualified student may receive access to KWS under certain conditions (see Muzlidoc procedure), and with formal approval from the appropriate head of the department.



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