Newsletter
Ethics Committee Research UZ/KU Leuven
Number 5 – April 2019

Dear researchers and teams

With this newsletter we wish to provide you information which can help you and us in optimally conducting and supporting high-quality clinical research with respect for the well-being and privacy of each patient and volunteer.

We wish you all a happy Easter!

Kind regards,

Ethics Committee Research UZ/KU Leuven
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1. Recognition of EC according to the national Law dated 7th of May 2017

In November 2018, the EC submitted an application to FAGG/FAMPH (Federal Agency for Medicines and Health Products) for recognition according to the new national law (*Wet betreffende klinische proeven met geneesmiddelen voor menselijk gebruik*) of 7 May 2017, art.6 §3-5.
In view of this recognition, the EC was also inspected by 2 FAMHP auditors on 27th of March 2019. As a result of the application and the GCP inspection, FAMPH confirmed our recognition according to the new law of 7 May 2017.

2. Change PI

We would like to point out that a change in Principal Investigator must be submitted to EC. Since this is considered as a substantial amendment, an EC approval is mandatory prior to implementation on site.

Please note that no actions will be taken by CTC until the PI change has been submitted to and approved by EC.

3. Good Clinical Practice (GCP)

EC would like to iterate that training in ICH GCP guidelines is mandatory for every PI, but also for each member of his/her study team. It is the responsibility of the PI to make sure that all members of the study team are trained and conduct the study according to ICH GCP.

The CV of the PI should explicitly mention the date when the most recent ICH GCP certificate has been granted (***max. 3 years***) and the organization**,** or alternatively, a copy of the ICH GCP certificate should be included in the submission of the study file.

The Biomedical Sciences Group at KU Leuven regularly organizes ICH GCP trainings related to research. The upcoming trainings are planned to take place in UZ Leuven on the 3rd of May 2019 and the 4th of September 2019.

Subscription is requested and can be done via https://uzleuven.learn.taleo.net/ (Leercentrum).

4. Master's thesis

Via an online application (SCONE), each student within the Biomedical Sciences group has to determine, based on a number of questions, whether his/her master's thesis requires further ethical review. In any case (and also if no explicit ethical approval is required and the project can

be automatically approved), the master's thesis must be registered in SCONE and can only start after the appropriate approval has been given.

If an evaluation by EC Research is necessary, the study must be submitted via the classical route: first to the CTC and once greenlight has been given, to EC.

5. Social media

We would like to draw your attention to the fact that EC should always be informed of the methods used to announce a study and recruit participants. These include both "traditional" channels (posters, leaflets, ...) and various forms of internet advertising (website, social media, ...). The necessary documents must be submitted for approval.

Please also check our recommendations about recruitment on our website: https://www.uzleuven.be/nl/ethische-commissie/onderzoek/adverterenrekruteren-richtlijnen
We expect that, after EC approval, every advertisement contains the message '*Approved by EC Research – Sxxxxx*', with the specific S-number mentioned.

6. Conflict of interest

In the CTC registration template, the PI is requested to indicate any conflict of interest for conducting the study by the investigator himself or herself and all members of his/her study team during the course of the study.
Hereby we would like to iterate the definition of "conflict of interest":

> ***Conflict of interest:*** *the situation in which the interests of a person to whom this law applies to, could influence the conclusions of an opinion/advice with the aim of obtaining an advantage, financial or not (such as acquiring a certain influence), directly or indirectly. This may include fees, reimbursements, participation in the profit or hospitality for the interested person him/herself, but also for his/her family or any other person with whom he/she has relationships. The benefits may also go to the organization for which he/she works (for example, a university service) or to which he/she is affiliated (for example, a professional organization), such as scholarships, payment of a staff member, allowances, a chair, etc.*
>
> https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/hgr_8891_beheer_belangenconflicten.pdf

7. Radiation exposure

When a participant is exposed to radioactive radiation in the study, we ask you to mention the amount of irradiation in the Informed Consent Form (in 'mSv'), as well as to compare this amount with the annual natural exposure.

8. General Data Protection Regulation (GDPR)

The 5 basic principles of the GDPR (General Data Protection Regulation – art.5) are:

1) purpose limitation: data can only be collected for a specified and explicit purpose and may not be further processed in a manner that is incompatible with the above mentioned purpose. In addition, a legitimate ground should be defined for data collection and processing.
2) Necessity: only data can be collected which are required for the purpose for which they are collected and processed and not 'nice to know' for that purpose.
3) Transparency: data are to be processed in a transparent manner in relation to regulatory authorities, control bodies and, last but not least, the data subject. This can be done through e.g. information brochures, registers, participant information letter. New participant information letter templates can be found here. The modalities for sending an information letter will be detailed in the UZ Leuven policy document.
4) Storage limitation: Data can only be stored as long as required for the purpose. Maximum periods should be specified.
5) Integrity and confidentiality: processed in a manner that ensures appropriate security of the personal data; e.g. access limitation, audit trail/logging, pseudonimisation, …

The sponsor of the study is responsible for compliance with these principles.
Please be informed that due to UZ Leuven policy (which will soon be available at muzlidoc), also all retrospective studies must be submitted to EC Research.

Several information sessions and walk-in sessions will be organized in April, May and June to clarify the practical implementation of GDPR in research, and more specifically about the handling of personal data in clinical studies in UZ Leuven. Specific communication will follow and will also appear on our website.

9. Cover letter

We would like to ask the principal investigators to pay extra attention to the cover letter that must be submitted to EC with each new study/substantial amendment.

- Please state briefly, but clearly, the reason for the substantial amendment in the cover letter when submitting an amendment.
- Please make the cover letter specific for UZ Leuven by for example clearly stating which optional tests of the study will be conducted in UZ Leuven (e.g. will UZ Leuven participate in the pediatric study, in the PK-study…?). Please also mention which sites will participate in Belgium.
- The principal investigator can mandate person(s) of UZ/KU Leuven to sign and submit to the Ethics Committee Research in his/her name. This mandate is valid for one year as from the date of last signature on the delegation mandate cover letter (see website EC).

10. Approval EC valid for 1 year

The EC approval given for a specific project, is valid for one year. In case no participants have been included during the first year after EC approval, the study will need to be re-evaluated by the EC. Inclusion of participants can be confirmed through the annual progress report. Please be informed that if the EC is not notified of the above, the study will be administratively closed.
This measure came into place as a result of the above mentioned FAMPH inspection.

11. ICF addendum versus adapted ICF in amendments

In case of amendments to the information provided to the participants (ICF), it is strongly advised to use an ICF addendum for *ongoing participants*. The ICF addendum lists only the changes or new information which is clearer to the participant than an amended ICF where changes are highlighted.
When inclusion is still ongoing, an amended ICF is required for *new participants*.

12. Name of KU Leuven (cf. Newsletter Research)

KU Leuven is the only correct name for the university and should always be mentioned first.
'Universiteit Leuven' or 'University of Leuven' cannot be used.
'Catholic University of Leuven' can be used, if preceded by 'KU Leuven' when reference to the Catholic identity of KU Leuven is of decisive importance in a given context.

13. Contact EC Research UZ/KU Leuven

EC Research can be reached by telephone between 10 am and 11 am or preferably by email via ec@uzleuven.be. This email address should also be used for new applications. ec-submission@uzleuven.be will not be used anymore.

Info

Information

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