Newsletter
Ethics Committee Research UZ/KU Leuven
Number 9 – April 2020

Dear researchers and teams

With this newsletter we would like to share some tips and tricks enabling 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 and, especially, a healthy Easter.**
**Take good care of yourself and your family and stay safe!**

Ethics Committee Research UZ/KU Leuven

Members: Dominique Bullens, Ariel Alonso Abad, Pascal Borry, Guy Bosmans, Xavier Bossuyt, Simon Brumagne, Jean-Jacques Derèze, Lut De Groote, Theresia De Fraye, Jan de Hoon, Lia De Wilde, Stefanie Goris, André Loeckx, Ben Nemery, Eva Puttevils, Marleen Renard, Katrin Roggeman, Miet Schetz, Karin Sipido, Anne Smits, Mathijs Swaak, Josse Thomas, Anne Uyttebroeck, Liliane Vandergeeten, Marilien Vandeputte, Veerle Vanparys, Ben Van Calster, Kristel Van Landuyt, Jan Verhaegen, Gregor Verhoef, Minne Casteels

Staff: Valerie Alderweireldt, Eveline Claes, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Greet Verbeeck, Sofie Vervoort

This newsletter is divided in two parts. In the first part, we will give you more information about the impact of COVID-19 on clinical trials. The other part contains information about trials in "regular" times.

## COVID-19

The past few weeks have been dominated by COVID-19. This also has a major impact in the field of clinical trials. We summarize some important guidelines but we refer to our website which is updated daily, for the complete guidelines and instructions.

EC Research emphasizes that in the context of clinical trials, the guidelines imposed by the government with regard to precautionary measures for COVID-19 must be respected. The (inter)national guidelines for clinical trials during COVID-19 can be found on our website.

**Submitting a (new) clinical trial application for the treatment or prevention of COVID-19**

1. An accelerated procedure is in place for the evaluation and approval of (new) clinical trial applications for the treatment or prevention of COVID-19. If the clinical trial is submitted as a pilot project within the CTR, the Federal Agency for Medicines and Health Products (FAMHP) commits to validate and review in four working days, as will do the evaluating EC (not including questions and your subsequent answers).

2. Submitting documents via CD-Roms is not recommended. EC Research cannot guarantee that these documents will be evaluated in time because the staff of EC is teleworking as much as possible. Please provide the documents **electronically**. If applicable, always mention "COVID-19" in the subject of the e-mail.

3. When registering your study via CTC, please put EC research (ecstaf@uzleuven.be) and (if applicable) the Biobank (Wetenschappelijke.BiobankUZLeuven@uz.kuleuven.ac.be) directly in cc.

**Other guidelines**

4. Non-urgent visits, studies, contacts, group discussions, interviews,… should be avoided and/or postponed. An alternative may be to contact the participants by phone/telemedicine visits.

5. In cases where a continued supply of trial medication needs to be maintained at home, trial medication may also be shipped directly, under responsibility of the principal investigator, from the trial site to the trial participants via courier. This is only possible provided that the product is suitable for transport, storage at home and administration at home.

   Please follow the internal guidelines of UZ Leuven if you consider this: Rechtstreeks afleveren van studiemedicatie aan patiënten onder uitzonderlijke omstandigheden (COVID-19).
   For the protection of the rights (confidentiality) of the participants, study medication may never be shipped by the commercial sponsor (or CRO) to the patient.

6. A temporary halt (recruitment/trial; globally/locally) should be submitted to the FAMHP and to the EC's of the participating sites within 15 days of the decision. A temporary halt is not a substantial amendment. A notification is sufficient.

7. When setting up a registry for a specific patient population during the COVID-19 pandemic, we ask you to coordinate with your colleagues in order to avoid that patients are enrolled in several overlapping registries. A list of the approved registry studies can be found via the link below. A generic informed consent for all these COVID-19 related registries has been developed by EC Research. If a patient has signed this, this consent applies to all COVID-19 related registries approved by EC Research and listed on its website.


Via this link, you can find the list of COVID-19 related studies approved by EC Research: https://www.uzleuven.be/nl/covid-19-studies-goedgekeurd-door-ec-onderzoek.

## Non COVID-19

### 1. Conflict of interest by EC-members

EC Research ensures that its advice is always formulated independently and in the interest of the trial participants.
The EC-members agree to sign a confidentiality agreement and a declaration of potential conflict of interest. These are publicly available on the EC website. They are renewed at least annually.

Conflicts of interest in a specific study (regarding the sponsor, location of the study and researchers, or persons who finance the clinical study, ...) are reported by the members to the chair before the discussion of the trial begins. When this is the case, the member will refrain from any intervention in the evaluation process.

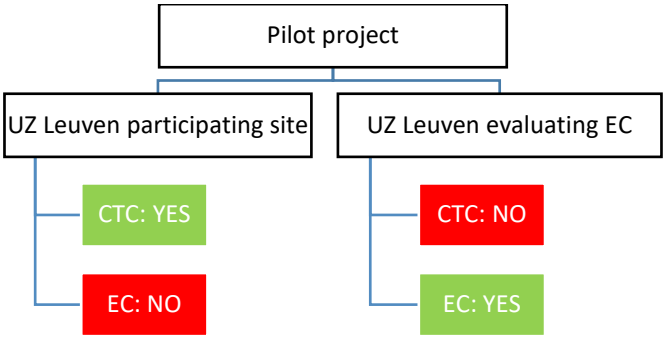
We would like to point out that on the other hand, also a principal investigator who submitted a study to EC Research, may indicate that a particular EC-member has a potential COI and should rather not be involved in the decision-making of his/her study.

### 2. Communication pilot projects

In 2021 or later, the European regulation will apply to all interventional clinical trials with medicines (CTR 536/2014). The objective of the CTR is to simplify and harmonize the submission and evaluation process of clinical trials applications across Europe. When the CTR applies, a study cannot be evaluated by the EC of a participating site. The study will be evaluated by an **independent EC**, selected by the CT College.

As a preparatory step before the implementation of the CTR, **pilot projects** are set up. Via the pilot projects, we can gain experience with the new regulation. Since May/June 2017, the first pilot projects are started according to the new legislation, with UZ Leuven as participating center as well as evaluating EC.

We would like to draw your attention to this scheme:




When UZ Leuven is a participating site in a pilot project, the study must be submitted to the Clinical Trial Center (CTC) but it will not be evaluated by EC Research. EC Research only receives minimal information about the study and about the evaluation by another EC. When the study team has questions about these studies, we encourage to discuss them with the sponsor of the study.

## 3. ICF diagnostic radiopharmaceuticals

When a trial is submitted with diagnostic radiopharmaceuticals (PET / SPECT imaging), the following consensus text, prepared by representatives of the Department of Nuclear Medicine, UZ Leuven and the Federal Agency for Nuclear Control (FANC), has to be included in the study's ICF:

(Paragraph "What is known about the tracer"):

> *In this study a tracer will be used in very low amounts that do not influence the normal processes in your body.*

(Paragraph "Radiation burden"):

> *Although in this study a tracer is used that is radioactively labeled, the amount of radiation to which you are exposed is low. Your radiation exposure will be approximately **x.x** mSv (millisievert) **for [the whole study] // [an injection of xxx MBq, with a maximum of x injections] [, including the radiation exposure of the CT(s)].***
> *The total radiation exposure of the body due to this study is **[lower than] // [comparable with]** the radiation exposure of for example a CT-scan of the abdomen, which is mostly between about 8 and 9 mSv. Also for comparison, the natural radiation exposure in Belgium is about 2 to 3 mSv per year. The safety risk of the radiation exposure that you get from this study, is regarded by experts of the ICRP (International Commission for Radiation Protection) as minor to intermediate. This exposure is lower than the dose constraint of 10 mSv, defined by the ICRP for medical exposure of healthy volunteers in biomedical research with moderate benefit aimed at diagnosis, treatment or prevention of disease in the future.*

*At this radiation exposure level the increased risk of health effects (i.e. cancer and/or leukemia) from radiation can be too small to be observed. There is no evidence that any risk exists for humans exposed to such low levels. It is assumed however that the risk rises with lifetime accumulated dose from all sources of ionizing radiation, including the doses you receive from medical procedures and the environment.*

*Taking into account the radiation dose due to your participation in this study, the additional risk is estimated to be maximally 1/2000. This risk is minimal in comparison to the natural occurrence of cancer. **[For volunteers/patients above the age of 50 years, the European Guideline for Radiation Protection no 99 (1998) "Guidance on medical exposure in medical and biomedical research" indicates that the constraint of 10 mSv may be increased by a factor of 5 to 10.]***

You can find this text on our website.

## 4. Online submission EC Research

From now on, the submission of an **initial** study to EC Research can be done electronically via our website. This is **not** yet possible for **(substantial) modifications**.

Submissions via email, Eudralink and liquid files are also still accepted. As already stated above in this newsletter, under the current circumstances we cannot guarantee the necessary continuity when documents are submitted via CD-Rom.

## 5. Contact persons

We would like to remind you to always provide us with the right contact persons related to the submitted dossier. Only these contact persons will receive all the communication from EC Research. Please also pass this message on to the sponsors of the studies. When a study member is not listed as contact person, he/she will not receive our communication.

info

**Information**

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