UZ LEUVEN

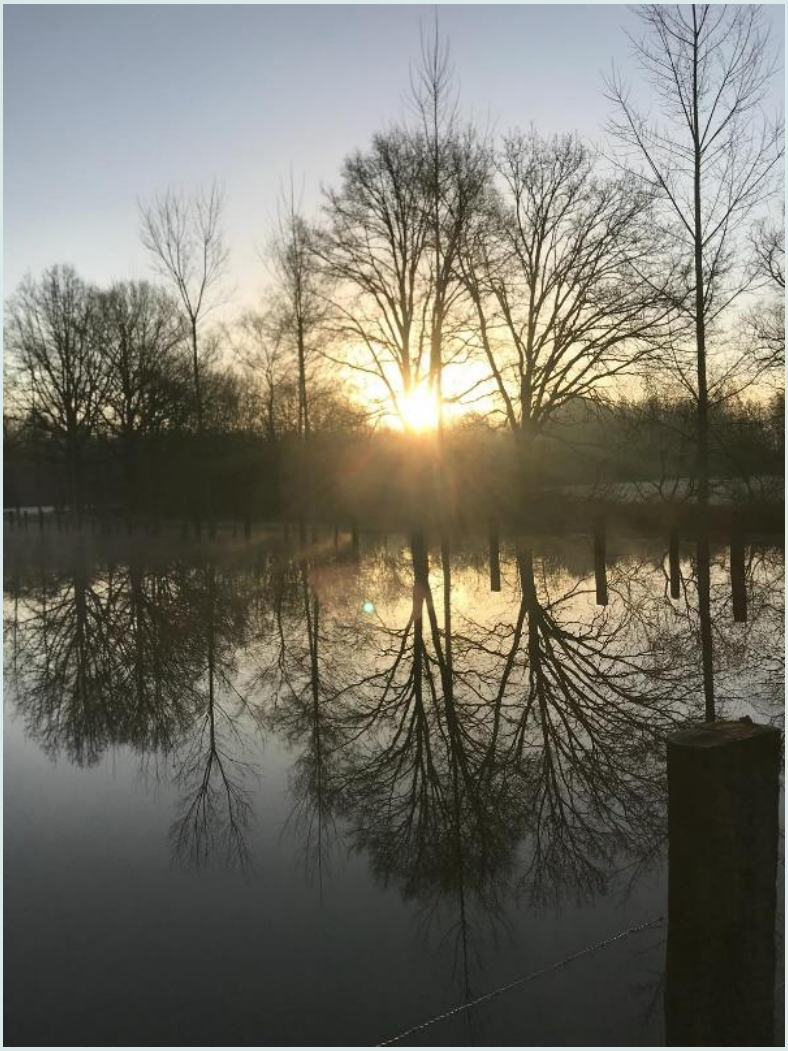
**Newsletter**
**Ethics Committee Research UZ/KU Leuven**
**Number 11 – December 2020**

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 all a Merry Christmas and a happy and healthy 2021!***

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, Lut De Groote, Theresia De Fraye, Jan de Hoon, Aernout De Raemaeker, Lia De Wilde, Stefanie Goris, André Loeckx, Koen Luyckx, Ben Nemery, Eva Puttevils, Marleen Renard, Angélique Rézer, Miet Schetz, Karin Sipido, Anne Smits, Mathijs Swaak, Josse Thomas, Anne Uyttebroeck, Liliane Vandergeeten, Marilien Vandeputte, Veerle Vanparys, Ben Van Calster, Kristel Van Landuyt, Katelijne van Overwalle, Jan Verhaegen, Gregor Verhoef, Minne Casteels

Staff: Stephanie Brams, Eveline Claes, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Sofie Vervoort

## 1. Modify the GDPR questionnaire

In order to facilitate the contract review by the legal department (if applicable) and to allow a privacy check by the ethics committee you will be requested (see message in the email of CTC in which the assigned S-number is mentioned) to complete the GDPR questionnaire.
The GDPR questionnaire needs to be completed for each study or research project for which UZ/KU Leuven acts either as sponsor or as participating site and in which personal data are processed.
A copy of the duly completed GDPR questionnaire is a necessary part of a submission to EC Research. This implies that the copy should be included in the submission package sent to the EC research. When EC has remarks about the GDPR questionnaire, please be aware that a **new** questionnaire needs to be filled in online, via this electronic link. Modify an existing questionnaire is currently not technically possible.
Please also remember that EC does not receive the questionnaire automatically. Please send us the questionnaire in PDF.
If you wish to submit an amendment to the EC for a study for which no GDPR questionnaire was completed yet because it was not required at that time ("pre-GDPR": rule of thumb this concerns studies with an S-number created before "S63291"), we ask you to regularize the GDPR aspect of the study by submitting the GDPR-questionnaire to EC in the next amendment to that study (and, when applicable, an amended ICF with appropriate GDPR wording).

## 2. Requests for secondary use of (personal) data and/or samples

At EC Research, we regularly receive requests for secondary use of (personal) data and/or samples that have been collected in prospective academic studies with UZ Leuven as sponsor and which researchers now want to share with other research partners (academic and/or commercial) in the context of new scientific research projects.
Although in some cases consent has already been obtained from the participant to the original study for the sharing of his/her data and/or samples in the context of new scientific research projects, an approval of EC Research will still be required (and a new S-number will need to be registered in such case, unless the new scientific research projects can be construed as an amendment to the original study – see below). This process is in accordance with the Belgian Law on Human Body Material (art. 20-21 requiring approval by an independent ethics committee as approved under the Belgian Law on Experiments) and hospital's policy regarding processing of personal data for research purposes (requiring amongst others a "privacy" check by EC Research in accordance with GDPR).

In such case, EC Research will, amongst others, assess the following aspects before being able to approve the sharing of such data and/or samples/data with research partners:

- The ICF given by the participants in the original prospective study (primary use) must have foreseen that (pseudonymised) data and/or samples collected within the study could be further shared with research partners (academic and/or commercial partners, inside and/or outside the EU, as the case may be);
- EC Research will review whether the research question of the new research project(s) is in line with the research question(s) of the original study;

- The role of UZ Leuven and the research partners in the new research project(s) shall be examined by EC Research. If the sponsor of the new research project(s) is not UZ Leuven, the new research project(s) cannot be set up as an amendment to the original study and will require a new S-number and approval by EC Research;
- The necessary contractual arrangements will need to be in place between UZ Leuven and the research partners to cover the envisaged secondary use of data and/or samples (such as a DTA or MTA/DTA or even a service agreement – templates can be found on CTC's website).

## 3. Compensation for subjects participating in a clinical study

When a subject participates in a clinical study, he/she should not have any costs except those related to the standard of care treatment of their disease.
The subject can however receive a compensation for time investment, efforts and expenses such as travel costs, meals,… . EC would like to see the details of the total amount received by the subjects.
The sponsor should therefore clearly specify which expenses will be compensated and the amount of each compensation, e.g. travel costs: a fixed amount per visit, the amount per km or the reimbursement of the exact costs,…
An example to which level of detail the compensation should be provided, is listed below:

| **Type** | **Amount** |
|---|---|
| Mandatory contraception | Reimbursement of patient's cost |
| Travel costs | [number] EUR per visit |
| Fuel | [number] EUR per kilometer (trajectory domicile-site) |
| Parking | Reimbursement of fee |
| Public transport | Reimbursement of fee |
| Meals | [number] EUR per visit |
| Medication needed to treat side effects | Reimbursement of patient's cost |
| Sun cream | Reimbursement of patient's cost |
| Time investment and efforts | [number] EUR per visit / trial |
| Hotel costs | [number] EUR per stay |
| … | |

EC invites you to make the compensation process as easy as possible for the patient (e.g. a fixed amount).
Some working parties are in the process of creating more guidance and harmonization about compensation for trial participants (BAREC, CT-College), and we will inform you of the outcome in due time.

## 4. What are the requirements to be PI within UZ Leuven?

As agreed by the Clinical research Board UZ Leuven (CRB), these requirements will be published shortly in Muzlidoc UZ Leuven and on our website.

## 5. Study access to medical files

EC Research re-emphasizes the importance of respecting the rules for study access to medical files of patients:

- only by a qualified person for a specific S-number in a flagged patient
- it is absolutely forbidden to use another person's login or to hand over a login to another person.

## 6. Template protocol IMP

On the intranet page of the CTC (https://wiki.uz.kuleuven.ac.be/display/ctc/Documenten) there is a link to a protocol template for an interventional study with an investigational medicinal product when UZ Leuven is the sponsor. From 1 January 2021 it will be mandatory to use this template for such trials.

## 7. Guidelines for preparing interventional studies and observational studies

### Interventional studies

The SPIRIT 2013 Statement provides evidence-based recommendations for the minimum content of a interventional study **protocol**.

SPIRIT 2013 builds on other applicable international guidance by citing empirical evidence and providing additional recommendations. It adheres to the ethical principles mandated by the 2008 Declaration of Helsinki, and encompasses the protocol items recommended by the International Conference on Harmonisation Good Clinical Practice E6 guidance. SPIRIT stands for an international, collaborative initiative of trialists, methodologists, journal editors, and ethicists from academia, industry, and funding agencies.

It helps to improve the completeness and quality of study protocols. We notice that many protocols do not fully address important study elements. Incomplete protocol content can impair understanding and implementation of the trial; reduce efficiency of protocol review; and lead to burdensome protocol amendments.

The recommendations are outlined in a 33-item checklist.

## Observational and non-interventional studies

A lot of biomedical research is observational. A checklist for protocol preparation is forthcoming, called SPIROS. In the meantime, the checklists for reporting of observational studies can be helpful to guide the preparation of the protocol for such studies.

The **reporting** of observational studies is often inadequate, which hampers the assessment of its strengths and weaknesses and of a study's generalizability. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Initiative developed recommendations on what should be included in an accurate and complete report of an observational study. STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of **STrengthening the Reporting of OBservational studies in Epidemiology.**

Observational research comprises several study designs and many topic areas. The STROBE statement is a checklist of items that should be addressed in articles reporting on the three main study designs of analytical epidemiology: cohort, case-control, and cross sectional studies. The intention is solely to provide guidance on how to report observational research well: these recommendations are not prescriptions for designing or conducting studies.

The recommendations are outlined in a checklist.

STROBE is the key and most broad checklist, but not the only guideline that can be useful. For example, there is also STARD for diagnostic accuracy studies, or TRIPOD for studies that focus on the development or validation of prediction models.

## 8. Studies in which UZ Leuven acts as sponsor and VIB is involved as partner

For each specific research project with VIB, an MTA/DTA must be completed and signed. In collaboration with CTC, LRD and VIB templates have been created, which will soon be available on our website.
In addition, a specific wording in the ICFs has also been agreed. This will also be available on our website.

info

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