UZ LEUVEN

Newsletter
Ethics Committee Research UZ/KU Leuven
Number 10 – July 2020

Dear researchers and teams

With this newsletter we would like to support and help 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 wonderful and, especially, a healthy summer.

Ethics Committee Research UZ/KU Leuven

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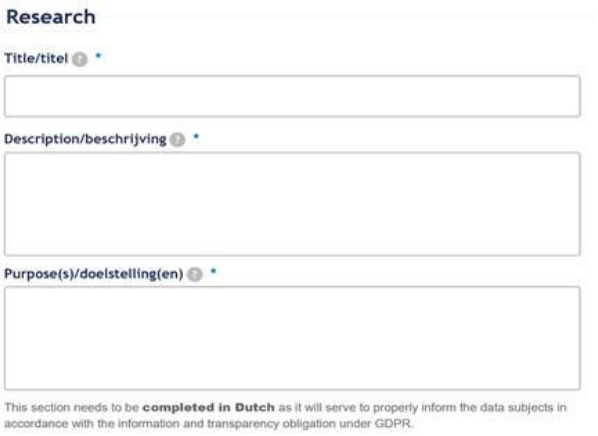
1. COVID-19

The past few months have been dominated by COVID-19. This also has a major impact on clinical trials. 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.
As of May 18th, research activities can be restarted, with a phased approach.
Study or sponsor specific instructions should be followed, provided that these do not conflict with the directives issued by the Belgian authorities, or those issued by UZ Leuven.

2. The use of Mynexuzhealth to inform patients/study participants in accordance with GDPR

UZ Leuven is committed to responsible processing of information relating to individuals and to respecting individuals' rights to data protection and privacy. Each research project involving the processing of personal data will need to be submitted to EC to allow for a "privacy check".
A "**GDPR questionnaire**" has been developed to facilitate such a privacy check and will form an integral part of the registration process at the CTC and EC. The GDPR questionnaire needs to be completed for each study or research project where UZ/KU Leuven acts as sponsor or as participating site and where personal data are used. Please note that a completed GDPR questionnaire will be required for a submission to EC.
The GDPR questionnaire and the guidance document for completing such questionnaire can be found on the CTC's website: http://wiki/display/ctc/GDPR.[1]
Apart from facilitating the privacy check, this GDPR questionnaire will serve another goal: comply with our information duty as data controller towards the study participants/data subjects (transparency): i.e. **provide a description of the purpose/goal of the research in layman's terms (art 13 and 14 GDPR).** The sections under 'Research' in the GDPR questionnaire will automatically be included in Mynexuzhealth.



[1] In case KU Leuven processes the data without UZ Leuven being controller or processor then this is to be indicated on the GDPR questionnaire and subsequently the PRET questionnaire will need to be completed and submitted to the EC by the researcher: https://www.kuleuven.be/pret/en/form?Filter=EN_UZ (contact: pret@kuleuven.be).

Study participants will thereby be informed about the (prospective and retrospective) studies in which their data are being processed after they are flagged with the corresponding S-number in KWS.
The patients will be able to see in Mynexuzhealth the list of all the studies with UZ Leuven as sponsor (and hence data controller) for which his/her data were used.
This way of informing patients is of utmost importance in retrospective studies as retrospective studies do not fall within the scope of the Belgian law on experiments and hence no ICF is required pursuant to said law. However, in accordance with UZ Leuven policy, registration at the CTC (including completing the GDPR questionnaire) and submission to the ethics committee (EC) is required in order to allow for a privacy check by the EC. Flagging study participants with the corresponding S-number in KWS is therefore also required in case of retrospective studies.
The (individual) information duty, imposed by GDPR, will now be complied with through Mynexuzhealth. A separate information letter is not necessary anymore in case of a monocentric study with UZ Leuven as sponsor/data controller. Also in case of a multicentric study with UZ Leuven as sponsor/data controller the use of Mynexuz will avoid a separate information letter to our patients/study participants. For patients/study participants of other sites not using Mynexuzhealth an information letter will still be required, distribution of which can however be delegated to the sites.

3. Cover letter

We already mentioned in our newsletter of April 2019 the importance of a good cover letter that must be submitted to EC with each new study/substantial amendment. We would like to emphasize this again.

- Please make the cover letter specific for UZ Leuven by e.g. clearly stating which optional parts 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).
- (In case of a substantial amendment): Please state clearly the reason for the substantial amendment in the cover letter.

4. Electronic application of new clinical studies to CTC

As of July 1st, the clinical trial center (CTC) will no longer accept study applications by e-mail. From that date, study applications must be submitted electronically via the website: https://www.uzleuven.be/nl/clinical-trial-center (“registreer nieuwe klinische studie”).
This step in automation will contribute to a faster and more efficient flow and processing of study applications.

For the time being the electronic application form is only available in Dutch. In the future there will also be an English version.
All studies that were submitted to CTC by e-mail before July 1st will of course be followed up further. The study team and the researcher do not have to take any additional action.
As a reminder: the submission of an initial study to EC Research can also be done electronically via our website, and this is the preferred method of submission. This is not yet possible for (substantial) modifications. Although receipt of CD-Rom submissions may not be possible in case of (another) lockdown, till further notice, submissions via CD-Rom, email, Eudralink and liquid files are still accepted.

5. Informed Consent Form templates

An experiment may only be started after participants have been informed and have given their written consent to participate in the study (cf. article 5 of the Experiments Act of 7 May 2004). The information and consent form should therefore be submitted to EC.
EC research strongly recommends the use of ICF templates.
On our website the following templates can be found:

- Template for EudraCT-studies (+ a separate one if UZ Leuven acts as the sponsor of the study);
- Template for non-interventional studies non-EudraCT-studies (+ a separate one if UZ Leuven acts as the sponsor of the study);
- Template for interventional non-EudraCT-studies (+ a separate one if UZ Leuven acts as the sponsor of the study).
- Template for case reports

These templates are designed by a working group made up of representatives of BAREC (Belgian Association of Research Ethics Committees), Pharma.be and patient associations.
We observed that researchers often use a wrong ICF template in which e.g. the fact of taking samples is missing or incompletely specified.
For example: for a study in which samples are taken from the participant, the researcher uses a template that does not contain this aspect, such as for an observational study (Template for non-interventional studies non-EudraCT-studies). Result: no appropriate ICF, and delayed EC-approval.

6. All previous newsletters can be found on the EC website

https://www.uzleuven.be/nl/ethische-commissie-onderzoek/nieuwsbrieven-ec

info

Information

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www.uzleuven.be/ethische-commissie/onderzoek
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