Fast-track procedure for academic COVID-19 studies

In reference to the communication of the chief physician of Ghent University Hospital (dd. 19MAR2020) about COVID-19 studies, he clearly states the following:

Studies on the prevention, diagnosis or treatment of COVID-19 can be initiated. Both HIRUZ and the Ethics Committee prioritize these dossiers following a fast-track procedure. **However, this is not an exemption to initiate these studies quickly without the necessary documentation or any assurances regarding patient safety.**

With regard to the latter, we specifically point out the necessary documents under step 1 of the procedure described below.

The fast-track COVID-19 procedure for academic studies is outlined in detail in the following steps:

1. **Preparation of your submission package**:

   Submission package for experiments:

   - Cover letter, signed by the PI (template: click here)
   - EC application form, signed (most recent version: click here)
   - Protocol (template: click here)
   - Informed Consent Form(s) (template: click here)
   - All documents provided to the subjects (e.g. recruitment material, flyers, posters, diaries, questionnaires, interview topic list…)
   - Data processing register (Ghent University Hospital studies: click here, Ghent University studies: click here)
   - Agreements *(if applicable – a draft version is sufficient)*
   - CVs of all local PIs *(if applicable – in case of a multicentric study)*
   - Insurance certificate *(only if Ghent University (Hospital) does not act as the sponsor of the study; otherwise provided by HIRUZ CTU)*

   Extra documentation needed for trials with medicinal products:

   - Protocol summary
   - IB, SmPC, IMPD of the IMP(s)
   - Secondary label(s) for the IMP(s)
   - Patient trial cards *(if applicable – if the participant is not under 24 hour supervision)*
   - GCP certificate of the PI at Ghent University (Hospital)
   - GCP certificates of all local PIs *(if applicable – in case of a multicentric trial)*
   - Clinical Trial Application Form *(if Ghent University (Hospital) does not act as the sponsor of the trial; otherwise provided by HIRUZ CTU)*
   - Letter of approval from the FAMHP *(if Ghent University (Hospital) does not act as the sponsor of the trial; otherwise provided by HIRUZ CTU)*
   - GMP-certificate *(if applicable)*

   Extra documentation needed for medical device trials:

   - List of essential requirements (listed by the FAMHP, click here)
   - Clinical Investigation Protocol (template: click here)

- Investigator's Brochure
- Instructions for use
- Device label
- CE-certificate *(if applicable)*
- GCP certificate of the PI at Ghent University (Hospital)
- GCP certificates of all local PIs *(if applicable – in case of a multicentric trial)*
- Application Form for medical device trials (click here) *(if Ghent University (Hospital) does not act as the sponsor of the trial: to be provided by the sponsor)*

2. **Simultaneous submission to HIRUZ CTU and the Ethics Committee (EC)**: please e-mail the completed and fully signed submission package simultaneously, in the same e-mail, to hiruz.ctu@uzgent.be and ethisch.comite@uzgent.be.

3. **Revision by HIRUZ CTU and the EC**: HIRUZ CTU will revise all documents and will provide their feedback directly to the EC. The **project number will be allocated** to you by e-mail by the EC.

4. **Feedback**: the EC will contact you directly in case of any questions or remarks. The combined feedback (from HIRUZ CTU and the EC) will be sent to you by e-mail. It is our goal to provide you feedback within two working days.

5. **Submission of adjusted documentation**: please answer in an e-mail to the EC with a response to all stated questions and remarks (adjust your study documents where necessary; don't forget to update the version numbers and dates). We expect your reply within five working days. Please make sure you put HIRUZ CTU in CC of your e-mail.

6. **Approval**: only if your adjusted documentation and additional information is deemed sufficient and the content acceptable, your study will be approved by the EC. Attention: your study can only start when a favorable opinion from the central EC has been obtained and as soon as all agreements are finalized (if applicable). In case your study is a clinical trial with medicinal products or a medical device trial, you can only initiate your study when you have received a favorable opinion from the FAMHP as well and when a Trial Initiation Visit has been performed by a CRA.

7. **Study initiation**: Please notify both HIRUZ CTU and the EC when your study starts (first study specific procedures performed/first ICF signed).

8. **During the study**: please provide an annual progress report to both HIRUZ CTU and the EC yearly. If you wish to modify your protocol while the study is ongoing, please contact HIRUZ CTU. You might need to submit an amendment to the study before implementing the change(s).

9. **End of trial report**: at the end of your study, please provide an end of trial report to both HIRUZ CTU and the EC, including the date of the last trial specific procedure performed, final number of participants and events of special interest.