Frequently Asked Questions (FAQ) about academic clinical studies after the imposed measures because of COVID-19 were adjusted at Ghent University Hospital

After the communication of the chief physician of Ghent University Hospital about clinical studies during the COVID-19 pandemic (dd. 19MAR2020), non-priority consultations and treatments were suspended, no new patients were recruited/included and no new studies were initiated at Ghent University Hospital.

In reference to his latest communication regarding this matter (dd. 28APR2020), the chief physician clearly stated the following:

> *a) New clinical studies*
>
> *Since the start of the crisis, you could only initiate new studies on the prevention, diagnosis or treatment of COVID-19. From May 4th, you can also initiate other clinical studies, in consultation with HIRUZ.*
>
> *b) Arrangement for companies*
>
> *Visitors from companies (representatives, monitors, auditors, CRA) may only come to the hospital if this is necessary for patient care. That arrangement has been extended until May 18th.*
>
> *Addition from the chief physician (dd. 13MAY2020): From Monday May 18th on, in case contact by telephone or digital contact is deemed insufficient, visitors from companies (representatives, monitors, auditors, CRA) may come to the hospital again. Visitors have to follow the guidelines concerning distance and hand hygiene.*

With regard to these guidelines, we received many questions from investigators about their academic trials and the actions to be taken.

The most frequently asked questions are summarized on the next pages.

I. Initiation of new clinical studies not concerning COVID-19

Q: “I want to initiate a new study that does not concern COVID-19. Do I have to get the approval from HIRUZ?”

A: HIRUZ does not approve or reject any studies. You do of course need a favorable advice from the Ethics Committee(s) and if applicable, from the FAMHP (and/or FANC). As of Monday May 4th, new clinical studies can be initiated and recruitment and/or treatment of ongoing studies can be reinitiated. Nevertheless, this is only possible under the following conditions:

- Social distancing in waiting rooms and limiting the number of patients and healthy volunteers to a maximum of 1 person per 3 m^2;
- Provide face masks and hand cleanser for patients, volunteers and study staff;
- Make appropriate arrangements regarding blood sampling, radiology and other departments where experiments take place, in order to be able to respect social distancing at those places as well.

The department and the Principal Investigator of the study are responsible for taking these measures and complying with them. Principal and Coordinating Investigators of multicentric studies are requested to inform other participating centers in Belgium about the (re)start of the study. Keep in mind that safety always prevails.

II. Reinitiation of clinical studies not concerning COVID-19

Q: “From May 4th, investigators can initiate clinical studies that are not concerning COVID-19. Can I also reinitiate the studies I’ve put on hold because of the pandemic?”

A: Yes, but only if you take into account the conditions described above (under Q.I). We would like to emphasize that it is the responsibility of the department and the Principal Investigator to determine if the study can be reinitiated or not. Keep in mind that safety always prevails (for the patient as well as for the employees).

III. Remote questionnaires, interviews or surveys

Q: “For my (approved) experiment, I would normally perform face-to-face interviews. Because of the national measures taken by the government because of COVID-19, the interviews will now be conducted by phone. Do I need to submit an amendment to the Ethics Committee?”

A: Until May 10th, an exception was made and only a notification to the Ethics Committee was sufficient. From May 11th on, an **amendment** is needed. This applies to all experiments in which face-to-face questionnaires / interviews / … will be converted to a remote version. A reminder on how to correctly submit an amendment can be found on our website.

IV. Studies with interventions as well as questionnaires/interviews

Q: “A survey for the patient is a part of my (approved) experiment. Because of the COVID-19 measures taken by the government, I will put all other interventions on hold, but the surveys can be completed by the patient from home. Is it permitted to let them fill in these surveys while I put the rest of the experiment on hold?”

A: It is the PI's responsibility to determine to what extent the study is still scientifically relevant if only remote surveys/questionnaires/interviews will be performed while the other study-specific interventions are being stopped or put on hold. Often, the scientific value will be preserved only if the whole study is put on hold (temporarily). We emphasize that this decision lies with the PI. Nevertheless, you do need to **submit an amendment** if you wish to implement these kind of changes. A reminder on how to correctly submit an amendment can be found on our website.

V. Studies from (thesis) students

Q: "I am no longer allowed to perform the experiment concerning my thesis research because of COVID-19 measures taken by the government. I am considering to completely redefine my research subject. Do I need to submit an amendment to the Ethics Committee?"

A: No, you need to submit a **completely new request**. Until May 10th, an exception was made and the Ethics Committee handled these dossiers according to a fast-track procedure. From May 11th on, these dossiers will be handled as a standard new request, following the standard timelines as outlined in the Belgian law on experiments (from May 7th, 2004).