## Due to coronavirus epidemic, the following restrictions have been announced at HUS for the ongoing clinical trial execution

## **Background**

At the beginning of this year new coronavirus COVID 19 initiated disease epidemic in China. The general access to hospital area has been limited in order to secure health care functionality and to secure safety for patients and health care professionals.

Helsinki University Hospital (HUS) is a research hospital, there are ongoing clinical trials to investigate and treat study recruited patients. Due to actual COVID-19 disease epidemic, following restrictions have been announced for clinical study patients:

- no new patients will be recruited for studies, but ongoing studies will be aimed to be executed according to prevailing possibilities
- all planned study patients visits ( which are not obligatory to perform) will be moved into future. It is recommend to try to find alternative digital opportunities for monitoring/for control visits / and for documentation
- Investigator outside of HUS cannot enter to HUS premises.
   Essential study visits for patient treatment or otherwise required due study protocol will be managed by HUS investigator with similar principles as other necessary activity at HUS
- Research work can be continued with similar principles like other HUS work. Investigator can use the accepted study leave, but should be noticed, that in case needed study leave can be cancelled
- Clinical Research Institute HUCH Ltd; CRI (HYKS-Instituutti Oy)
  will negotiate with study sponsors about ongoing studies
  continuity according to above guidelines given at HUS hospital,
  including study monitoring. CRI will negotiate potentially
  needed clinical trial agreement amendments with sponsors
  according to needs arising project by project.
- The collection of biobank samples will be continued, if clinical situation allows it. Biobank samples are important matters in future, while investigating different morbidities related to corona-infection. If there remains an ability to collect biobank samples, it might in the future open possibilities to understand better details related to COVID-19 disease.
- Scientific research, including biobank activity together with Helsinki University, will be carried on, even under emergency conditions, in the scale as clinical treatment activity together with health care professionals and patients safety allows it.

## **Decision**

I have decided that clinical trial activity can be continued at HUS in the scale that is allowed by other ongoing daily clinical activity and if the safety of health care professionals and patients allows it to be performed. No new study patients can be recruited for now, but ongoing studies are planned to be executed according to protocols and prevailing possibilities. The study patient visits will be moved into future or will be replaced with other means according to possibilities. The external investigators are not allowed to enter into HUS hospital or into facilities which HUS is administering.

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Policy maker, Teppo Heikkilä, temporary Admin chief physician at HUS

Additional information

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