

**CAPACITY- COVID**

**Scientific research involving the new coronavirus**

Dear Sir / Madam,

You (or your relative) have received this letter because of a (possible) infection with the new coronavirus. You (or your relative) have (has) been admitted for treatment at [*name hospital*]. We urgently need to learn more about patients with (suspected) coronavirus for now and for future patients. Therefore, we collect medical information within a patientregistry. This letter informs you about the CAPACITY-COVID registry. Participation in this registry will not affect your standard care. If you wish to participate, you do not have to do anything or undergo additional investigations. The goal of this registry is to improve care for patients with the new coronavirus and provide a scaffold for future research. Please take your time to read this letter and, if needed, discuss this with your relative(s).

**What is this new coronavirus?**

In late 2019, people became ill due to a new type of coronavirus in Wuhan, China. This new coronavirus has officially been named SARS-CoV-2. The disease caused by this virus is called COVID-19. Symptoms of this disease include fever and respiratory complaints, like coughing and shortness of breath. In januari 2020, the World Health Organization (WHO) declared a the outbreak of this virus a medical emergency. Several countries have taken drastic measures to combat the spread of this virus to prevent it from overwhelming national healthcare systems.

**What is the CAPACITY-COVID registry?**

The current coronavirus is new. We know little about the disease COVID-19. What we do see is that the disease is highly variable in severity. Currently, we are unable to predict which patients become severely ill and which ones do not. It is of great importance that we study this disease to increase our knowledge as fast as we can. To make this research possible, the World Health Organisation (WHO) created a registry in which hospitals may collect (anonymous) medical information of patients who test positive for the coronavirus. It seems that patients with prior cardiovascular disease are at higher risk of becoming severly ill. The goal of the CAPACITY-COVID registry is to improve care for patients with the new coronavirus.

**What data are collected in the CAPCITY-COVID registry?**

The medical data that we collect of you (or your relative), includes the following: patient history (symptoms), history of pre-existing conditions, medicine use, results of bloodtests and microbiological tests (for example viruses and bacteria), results from diagnostic tests (for example CT-scans and MRI-scans) and the occurrence of any complications.

We use the data obtained through routine medical care. The care is at discretion of the treating team of physicians. This means that you (or your relative) will not undergo any extra interventions or tests as part of this registry. Likewise, you (or your relative) will not have to do anything for this registry. This registry does not affect the care that you (or your relative) is currently receiving.

**How do we protect your privacy?**

To protect your (or your relative’s) privacy, all identifiable data will be removed from your medical data. This includes your name, date of birth and patient ID. Instead, these are replaced by a code. This is called ‘encoding’ or ‘pseudonimisation’. Only those who have access to the key to this code, can trace back your identity. Only the coordinating researcher of your hospital has access to this key. The key and the medical data we collect will be kept in a secure location for at least 15 years. This is in case the data need to be verified at a later date. In this way we adhere to current legislature concerning your privacy.

**Opt-out**

Naturally, you have the right to object, if you do not wish your medical information (or the medical information of your relative) to be captured in this registry. This is called “opt-out”. If you (or your relative) do not wish to participate, there will be no consequences for the medical care you (or your relative) receive(s). Opting-out is possible by using the opt-out form. This can be found:

* On our website: [……]
* In the back of the information booklet [‘name booklet’] that you received upon admission to the hospital.

If you do not opt-out, we will automatically assume that you consent with the use of your medical data. This opt-out system was carefully considered during this exceptional situation. The reasons for choosing this sytem are:

1. The public health and health care systems are under great pressure due to the outbreak of the new coronavirus.
2. Severly ill patients cannot give consent for participation to scientific research due to the nature of the medical care they require. If only data of the less severely ill patients were used, this would not give a correct representation of the disease course of and the effects of treatment on COVID-19.
3. The National Institute of Public health advises to minimalise the number of direct contacts with patients to prevent the spread of the new coronavirus.

For any questions regarding the data collection, you can contact us with […….] by mailing us at [……..] or calling us on […….].

Yours sincerely, [……..]