

**ERACODA**

The ERA-EDTA COVID-19 Database

**Scientific research involving the new Corona virus**

Dear Sir / Madam,

You have received this letter because you or your relative is diagnosed with an infection with the new Corona virus. Next, you have (or your relative has) a chronic kidney disease, with need for dialysis or a kidney transplantation in the past. Because of the Coronvirus infection, you are (or your relative is) treated or admitted at [*name hospital*]. We urgently need to learn more about the COVID-19 disease in patients with kidney disease. Therefore, we collect medical information within a patient registry. This patient registry is called the ERACODA Database and is a European cooperation. Participation in this registry will not affect your care in any way. If you (or your relative) agree(s) to participate, you do not have to do anything or undergo additional investigations. The goal of this registry is rather to identify factors that are related to the severity of disease, to improve care for patients with COVID-19 in the future. The letter contains information about the patient registry. Please take your time to read this letter and, if needed, discuss this with your relative(s).

**What is this new Corona virus?**

In late 2019, people became ill due to a new type of Corona virus in Wuhan, China. This new Corona virus can cause a disease that is called COVID-19. Most patients with this disease have fever and respiratory complaints, like coughing and shortness of breath. This specific Corona virus is different from other Corona viruses that were already known. In januari 2020, the World Health Organization (WHO) declared a the outbreak of this virus a medical emergency. In the meantime, the virus spread around the world very fast and at this time, it caused a pandemic (a world wide epidemic). Several countries have taken drastic measures to combat the spread of this virus to prevent it from overwhelming national healthcare systems.

**Why the ERACODA registry?**

The Corona virus is new. Therefore we know little about the disease COVID-19. What we do see is that the disease is highly variable in severity between different paitents. Currently, it is unclear how COVID-19 behaves in patients with kidney disease. Kidney patients with need for dialysis because of little renal function have often reduced immunity. It could therefore be that COVID-19 is more severe int hese patients, but in fact there is a lot uncertainty about this. Kidney patients that received a kidney transplantation in the past, use immunnosupressives, and probably have therefore a higher chance of severe illness caused by a virus. However, it could be that little renal function or specific immunnospurresiva would lead to a less severe COVID-19 disease. Most symptoms are the result of a heavy reaction of the immune system on the virus. Because of this, kidneypatients using immunnosupressiva have probably a less severe disease. The goal of this ERACODA patientregistry is to obtain more knowledge about the course of COVID-19 in kidneypatients.

**What does the ERACODA registry mean?**

The ERACODA registry has been set up by the ERA-EDTA. This is the European coorperation of experts on kidney disease (European Renal Association – European Dialysis and Transplantation Association). The goals of the ERACODA registration is to obtain more knowledge about the course of disease in COVID-19 patients with kidney disease. In this way, we try to improve care for patients with the new Corona virus. To reach this, from as many as possible patients with COVID-19 and kidney disease medical information is registered in the patientregistry. It is very important to obtain data from patients which are very ill, but also from patients with a mild disease. In this way, we can learn a lot about factors that can influence or predict how the disease develops.

**What information is colleted in the ERACODA 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 blood- and virustests, 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. 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 that is present in your medical data will be replaced by a code. This includes your name, date of birth and patient ID. This is called ‘encoding’ or ‘pseudonimisation’. Only the coordinating researcher has access to the key of this code, and only with the key it is possible to trace back your identity. In case you are also registered in other local patientregistry, with the key, information from these other registries can be requested to make the medical information as complete as possible. In this way, we can also continue this research in the future, to study how COVID-19 can affect the renal function, illness and mortality. We adhere to current legislature concerning your privacy. The key and the medical data we collect will be kept in a secure location for at least 15 years. This is important to be able verify the collected data at a later date, in case that is needed.

**Opt-out**

Of course, you have the right to object, if you do not want 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 want to participate, that will have 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:

* As attachment to this letter
* On our website: <https://www.era-edta.org/en/covid-19-news-and-information>
* By sending an email to: [*e-mail address*]

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 system are:

1. The public health and health care systems are under great pressure due to the outbreak of the new Corona virus and more knowledge about COVID-19 is needed.
2. Severly ill patients often cannot give consent for participation to scientific research. If only data of the less severely ill patients are used, this will 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 Corona virus.

For any questions regarding the data collection, you can contact [*name contact person*], project coordinator of the [*name hospital*] by mailing at [*mail address*] or calling on [phone number].

[……signature....]

Yours sincerely,

On behalf of the ERACODA patientregristry team:

[Name, function]

[Department]

[Address]