

**ERACODA**

The ERA-EDTA COVID-19 Database

**Scientific research involving the new coronavirus**

Dear Sir / Madam,

You have received this letter because you (or your relative) is diagnosed with an infection with the new Coronavirus (COVID-19). 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 Coronavirus infection, you are (or your relative is) treated or admitted at [*name hospital*]. We urgently need to learn more about COVID-19 in patients with kidney disease. Therefore, we collect medical information in a patient registry. This patient registry is called ERACODA and is a European cooperative project. Participation in this registry will not affect your care (or the care for your relative) in any way. If you (or your relative) agree(s) to participate, you do not have to do anything or undergo any additional investigations. The goal of this registry is just to collect data that are obtained during routine clinical care to identify factors that are related to the severity of disease, to improve care for patients with COVID-19 in the future. This letter contains information about the patient registry. Please take your time to read it 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 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 Coronavirus is different from other Coronaviruses 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 Coronavirus is new. Therefore we know little about the disease COVID-19. What we do see is that the disease is variable in severity between different patients. Currently, it is unclear how COVID-19 behaves in patients with kidney disease. Kidney patients with need for dialysis because of low kidney function have often reduced immunity. It could therefore be that COVID-19 is more severe in these patients, but in fact there is a lot uncertainty about this. Kidney patients that received a kidney transplantation in the past, use immune system suppressing drugs, and may have therefore a higher chance of severe illness caused by a virus. However, it has also been suggested that low kidneyl function or specific immune system suppressing drugs may lead to a less severe form of COVID-19 disease. Most symptoms are the result of an exaggerated response of the immune system on the virus. Because of this, kidney patients using immune system suppressing drugs may actually have less severe disease. The goal of the present ERACODA patient registry is to obtiain more knowledge about the course of COVID-19 in kidney patients.

**What does the ERACODA registry mean?**

The ERACODA registry has been set up by the ERA-EDTA. This is the European society of experts in kidney disease (European Renal Association – European Dialysis and Transplantation Association). The goals of the ERACODA registration are to obtain more knowledge about the course of COVID-19 in patients with kidney disease. In this way, we try to improve care for patients with the new Coronavirus. To reach this goal, medical information will be collected from as many patients with COVID-19 and kidney disease as possible. It is very important to obtain data from patients who are very ill, but also from patients with a mild disease. Only when we collect data of all patients in an unbiased way, we can learn about factors that can influence or predict how the disease develops.

**What information is collected in the ERACODA registry?**

The medical data that we will collect of you (or your relative), includes the following: patient history (symptoms), history of pre-existing conditions, medicine use, results of blood- and virus tests, results from diagnostic tests (for example CT-scans and MRI-scans) and the occurrence of any complications. We will use only data obtained via routine medical care. This means that you (or your relative) will not undergo any additional 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, identifiable data that is present in your (or in your relativrs) medical record will be replaced by a code. We will therefore not collect your (or the name of your relative) name, date of birth and patient ID. This is called ‘encoding’ or ‘pseudonymisation’. Only the coordinating researcher has access to the key of the code with which it is possible to trace back your identity. In case you are also registered in other local patient registries, 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 for instance how COVID-19 can affect kidney function, illness and mortality in the long-term. 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.

**Informed consent**

We can only use your medical information for this patientregistry if you give written consent. Therefore, we ask for your consent in this letter. If you decide to give consent, you can withdraw your consent at any time. To do this, reach [name] via telephone number [phone] or via e-mail [mail]. If you decide to withdraw your consent, the medical information will be deleted from the registry for future use.

You can give informed consent by filling in the attached informed consent form for the ERACODA patient registry. If you sign the form, we will note in the medical record of you (or your relative) that you gave consent to use the medical information for the ERACODA registry. If you do not want to give informed consent, this will not influence your or your relatives medical care in any way.

**If you sign the informed consent form for your relative**

In medical research, if possible, we always try to obtain informed consent from the patient him- or herself. However, sometimes this is not possible. In that case we ask informed consent to a relative. In the case of the ERACODA registry, we included this possibility to be able to obtain also medical informations from patients who are very ill, and who themselves are not able to give consent. If we would obtain only informations of less ill patients, we will not be able to draw firm conclusions about disease progression and prognosis in patients with kidney disease and COVID-19. Also in case you give informed consent for your relative, it is always possible to withdraw consent at a later stage as mentioned earlier.

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 [phone number].

Yours sincerely,

[signature]

On behalf of the ERACODA patient regristry team:

[name,

Function,

address]