

Institutional Review Board (IRB)

[[Address]]

Dated: [[Date]]

Re: Establishing a COVID-19 Kidney Replacement Therapy (KRT) Database and eCRF

Dear Ethics Committee

On 31 December 2019, the WHO was informed of a cluster of cases of pneumonia of unknown cause detected in Wuhan City, Hubei Province of the People's Republic of China. Subsequently a novel coronavirus has been identified as the cause of their illness.

At present it is unclear whether patients on kidney replacement therapy (KRT), i.e. living with a kidney transplant or on dialysis, have worse outcome when infected with COVID-19. Initial data are conflicting, but we do know that these are vulnerable patients. However, KRT is already taken into account as risk factor when triaging patients to be admitted to an ICU or not. It is unknown what the risk factors for a worse prognosis are in this patient group. Knowledge on these risk factors may help to change treatment policies to improve prognosis in these patients.

In the past, clinical data on emerging infections has not been collected, standardized, or shared quickly enough to inform the outbreak response and patient care. Having learned from this experience, the European Renal Association – European Dialysis and Transplantation Association (ERA-EDTA) has now started an international initiative to collect data across Europe on patients with clinically suspected or confirmed infection with COVID-19. This initiative is called the ERA-EDTA COVID-19 Kidney Replacement Therapy (KRT) Database.

To fill this database an electronic case record form (eCRF) has been developed to assist with the collection of standardized clinical data, and that has undergone review and validation by international clinical experts. The eCRF is designed to collect data that can be easily obtained by review of hospital notes. This database is meant to analyze present patient care, in order to optimize it for the future. The study is purely observational. No biomaterial will be collected. No treatment or any other intervention is given. Given this nature, the IRB attached to the central Working Group that is located in The Netherlands, judged this initiative to be exempt of IRB approval and confirmed this in writing. Each patient to be entered in the database will get a unique identifier. Furthermore, we will ask to fill in the unique identifier with which these patients are already known in the international

Eurotransplant or in their national or regional renal registry. This will prevent that patients will be entered twice, and would allow record linkage in a later stage, when this would be needed.

The central electronic COVID-19 KRT Database uses REDCap software, which is a secure, state-of-the-art web platform for building and managing online databases, hosted by the University Medical Center in Groningen, The Netherlands. All information entered into the database will be pseudonymised and the employees that develop and run the database will not be able to identify patients from these records. Data ownership will remain with the Data Submitter. Data submitters are partners in the project and will be acknowledged accordingly as co-authors. The database will never be handed to other parties. After ending of the inclusion period, data will be returned to the data submitter and the database will be destroyed.

We would like to hear from the IRB whether this initiative is exempt of IRB approval. If so, could you please confirm this in (English) writing. If not, we kindly request your assistance with expedited review of this data collection tool to enable us to implement it as soon as possible in our **institution / country**.

Please don't hesitate to contact me if you require any further information.

Yours sincerely

[[Signature]]

On behalf of the ERA-EDTA COVID-19 KRT Database Initiative

[[Name]]

[[Address]]