**DATA TRANSFER AGREEMENT FOR**

**ERACODA**

- The **ERA**-EDTA **CO**VID-19 **Da**tabase for patients on kidney replacement therapy -

**By and between:**

1. University Medical Center Groningen (“**UMC Groningen**”), a not for profit educational and research organisation established by virtue of the higher education and research act (Wet Hoger Onderwijs en Wetenschappelijk Onderzoek) having its principal office at Hanzeplein 1, Groningen, the Netherlands, registered with the Dutch Commercial Register (Handelsregister) under number 01169570, lawfully represented by its Board of Directors,

**And**

1. [***name***], having an address of [***address***] (“**Data Provider**”), for the purposes of this Agreement legally represented by [***name***], [***function***],

each, individually, a “**Party**” and collectively, the “**Parties**”.

**Recitals:**

1. Parties are both healthcare providers;
2. UMC Groningen has, in collaboration with Radboud University Medical Center, University Medical Center Utrecht, Stichting Nefrovisie and Amsterdam University Medical Center (hereinafter together the “**Working Group**”), set up a database of patients with COVID-19 across Europe which has been established to answer questions on the prognosis and risk factors for outcome of patients on kidney function replacement treatment, as specified on “”LINK” (hereafter the “**Database**”) as set out in the Protocol attached as Exhibit A; and
3. The Working Group has appointed UMC Groningen as legal entity and, in particular, UMC Groningen employee, prof. dr. R.T. Gansevoort, as the supervisor under whose responsibility the conduct of the Database will be carried out (hereinafter referred to as the “**Principal Investigator**”); and
4. As a service to the research community, Data Provider wishes to disclose or make available to UMC Groningen certain Data (as defined below) and UMC Groningen wishes to utilize Data received from Data Provider in conjunction with the Permitted Purpose (as defined below), subject to the terms and conditions of this agreement (Agreement) and all applicable laws and regulations; and
5. UMC Groningen will also collect such cohort data from other parties. The full dataset in which all subdatasets are included will be used for analyses which are initiated by the Working Group; and
6. It is contemplated that the results of the analyses will be jointly published by the parties participating in the Database.

**The parties hereby agree as follows**

1. **Database and disclosure of Data**
	1. The aim of the Database is to collect Data (defined below) regarding health outcome and risk factors for complications in COVID-19 patients who are living with a kidney transplant or who are receiving dialysis treatment. By collecting this information in a standardized manner, the Database can aid in providing more insight in (1) the incidence of complications in patients on kidney replacement treatment with COVID-19, and (2) the vulnerability and clinical course of COVID-19 in such patients.
	2. Subject to the terms and conditions of this Agreement, Data Provider will disclose certain data as described in Exhibit B attached hereto (“**Data**”). The Data will be disclosed by Data Provider to UMC Groningen via Redcap.
	3. Data Provider agrees to disclose the Data solely to conduct the Database as set out in the Protocol attached as Exhibit A and to publish about the results of the Database (the “**Permitted Purpose**”) and for no other purpose.
2. **Data Privacy**
	1. Data Provider shall only provide such Data as necessary for the Database. The Parties recognize that any Data disclosed hereunder may constitute personal data as defined in the General Data Protection Regulation (EU) 2016/679 (GDPR), including personal data concerning health. The Dutch Health Inspectorate (in Dutch: Inspectie gezondheidszorg en jeugd) has confirmed to UMC Groningen that it recognizes the importance of health care providers to be able to deviate from applicable laws, regulations, guidelines and standards if this is required due to the crisis situation surrounding COVID-19. The Dutch Health Inspectorate has stated that such deviations are related to the importance of effectively combating the COVID19 outbreak, that a professional assessment has been made of the various interests at stake and that this has been recorded by UMC Groningen in a traceable manner. Data Provider represents and warrants that it has made its own assessment in this regard and that it agrees. The Parties therefore agree to the deviations set out in this clause 2 and the Protocol attached as Exhibit A.
	2. In line with the current position of the Centrale Commissie Mensgebonden Onderzoek (“CCMO”), UMC Groningen and Data Provider are each considered controllers for their processing of the personal Data and will both handle all personal Data in accordance with the GDPR and any other to the performance of the Database applicable laws or regulations covering the protection of personal Data (collectively “Data Protection Law”). The Parties will fully cooperate with each other as controllers and shall take the necessary measures in order to comply with the Data Protection Law. Such cooperation shall duly reflect the respective roles and relationships of the controllers in relation to the participants as data subjects, in particular as regards the data subjects’ rights and each Party’s duties to provide the information referred to in articles 13 and 14 of the GDPR and to report a personal data breach as defined in article 4 paragraph 12 GDPR and further determined by articles 33 and 34 of the GDPR. Each controller shall maintain a record of processing activities under its responsibility.
	3. The Data Provider warrants and undertakes that :
3. the Data have been collected, processed and transferred in accordance with the GDPR and additional data protection laws in the Netherlands;
4. that the Data will only contain Pseudonymised data and no directly identifing personal data;
5. it has obtained any regulatory or ethics approvals necessary to collect the Data and transfer the Data to the UMC Groningen;
6. it has full authority to transfer the Data to the UMC Groningen;
7. [Option 1] in accordance with article 458 of the Dutch Medical Treatment Act (WGBO), informed consent of the Data subjects is not required for this Database. Data will be collected on opt-out basis on the legal ground of article 9.1 sub g (processing is necessary for reasons of substantial public interest) and/or 9.1 sub i (processing is necessary for reasons of public interest in the area of public health) GDPR. It can be established that requesting consent for data processing from COVID-19 patients cannot reasonably be expected from the care provider / researcher, as:
* it is unsafe for the researcher and those around him to ask the patient for consent (due to the infectiousness of the disease);
* the patients are seriously ill;
* the care workers are overburdened with extra care tasks.

Patients have the opportunity to object to research with their personal data via the local opt-out register for research with clinical data and/or specific partient (relative) information letters.

[Option 2] Each Party shall be responsible for its own processing of personal Data in accordance with all data protection law and with the informed consent form obtained from Data subjects.

* 1. Upon Data Provider’s first request, UMC Groningen undertakes to no longer use Data for future research of individuals who have notified Data Provider that they no longer wish for their personal data to be processed or who have requested for erasure of their data and, to the extent legally required, UMC Groningen shall cause its subcontractor to erase the data concerned.
1. **Data Security and Confidentiality**
	1. Data Provider acknowledges that the Data will be disclosed to UMC Groningen via the online facility of Redcap. UMC Groningen will provide Data Provider with a personal login key to upload the Data in the Redcap online facility of UMC Groningen. Data Provider represents and warrants that all employees wo will receive the login key via UMC Groningen shall not give their personal login key and/or password to any other person without UMC Gronigen prior written approval.

3.2 UMC Groningen shall ensure that all employees, agents, and (sub)contractors with access to the Data comply with the terms of this Agreement, as well as any applicable data privacy and security laws and regulations. UMC Groningen shall ensure that only those of its employees directly concerned with the Permitted Purpose have access to the Data and that they shall be bound by confidentiality and user undertakings and limitations substantially similar and no less stringent than those provided for in this Agreement.

3.3 UMC Groningen shall not disclose Data to any third party without the prior written consent of the Data Provider (excluding the Working Group collaborators).

1. **Intellectual Property Rights**
	1. UMC Groningen acknowledges that, as between UMC Groningen and Data Provider, all Data received by UMC Groningen from Data Provider in connection with this Agreement shall be and remain the sole property of Data Provider, subject to the rights of use granted to UMC Groningen hereunder.
	2. Data Provider hereby grants UMC Groningen a non-exclusive, non-transferable, worldwide, perpetual, fully paid-up and royalty-free right and license, for the Permitted Purpose only to receive, analyze, utilize, copy, store, commingle and process the Data solely for the Permitted Purpose.

All discoveries, developments, databases, inventions (whether patentable or not), methods, reports, know-how, or trade secrets which are made by the Working Group as a result of the conduct of the Database shall be jointly owned by the members of the Working Group.

1. **Termination and effects of termination**
	1. Either Party may terminate this Agreement upon written notice to the other party with immediate effect in case of any breach of or failure to comply with any of the terms or conditions of this Agreement by the other Party, which breach or failure, if capable of remedy, is not remedied within thirty (30) days after notice from the aggrieved Party demanding such remedy.
	2. Upon termination of this Agreement, UMC Groningen shall, upon the written request of Data Provider, either return or destroy all Data received from Data Provider, and UMC Groningen shall not retain any copies of such Data; provided, however, that Data may be retained for continued use by UMC Groningen to the extent that any portion of such Data (i) is incorporated in any publications or draft publications or any other derivative works generated by, or for, UMC Groningen or (ii) is necessary to comply with all applicable laws and regulations as well as UMC Groningen’s internal document retention policies aimed at legal, corporate governance or regulatory compliance, and only to the extent any such retained Data shall remain subject to the disclosure and use restrictions set forth herein.
	3. The confidentiality rights and obligations set forth in this Agreement will survive termination of this Agreement with five (5) years, except that with regard to any personal data these obligations will survive indefinitely.
2. **Liability**
	1. UMC Groningen will perform the Database in accordance with all applicable laws and regulations and to the best of its ability.
	2. The Parties agree that to the maximum extent permitted by applicable laws and regulations, in no event will any Party (including its affiliates and subcontractors, and their respective directors, officers, and employees) be liable for any indirect, special, consequential, incidental, punitive or non-contractual damages (including without limitation damages for lost profits, loss of revenue and loss of business opportunities and lost data) arising out of or related to this Agreement.
3. **Publication**

7.1 Collaborators who contribute Data will be recognised on any resulting publications as PubMed-citable contributing author. A corporate authorship model will be used. Example: [https://pubmed.ncbi.nlm.nih.gov/29554312](https://pubmed.ncbi.nlm.nih.gov/29452941)

7.2 If, from the journal in which the results are to be published, there are restrictions on the number of author spaces allowed, the publication will be in accordance with academic standards (as set out in the guidelines available at www.icmje.org).

1. **Miscellaneous**
	1. Neither Party may assign or delegate its rights or obligations under this Agreement, in whole or in part, without the prior written consent of the other Party.
	2. This Agreement will be construed and enforced in accordance with the laws of The Netherlands, without regard to any choice or conflict of laws. In case a dispute may arise out of or pertaining to this Agreement, the competent courts ofthe Northern Netherlands, shall have exclusive jurisdiction.

8.3 A Party shall not be held liable or considered in default of its obligations hereunder if it is affected by failure or delay due to natural disasters, war, acts of terrorism or any other cause beyond the reasonable control of a Party (“Force Majeure”). The Party affected by Force Majeure shall promptly notify the other Party in writing on the circumstances of Force Majeure, what is being undertaken by the affected Party and when the Force Majeure is (expected to be) resolved. Such non-performance or delay is excused under this provision only for the duration of the qualifying Force Majeure.

[Signature page follows.]

**Executed by the Parties**:

**UMC GRONINGEN:**

By:

Title:

Date:

Signature:

**For read and acknowledged:**

The undersigned UMCG employees hereby declare that he has read the above Agreement between the Parties and that he agrees with the provisions of the Agreement relative to his role, responsibilities and duties concerning the transfer, handling and use of Data for the Database:

By: Prof. dr. R.T. Gansevoort

Title: Principal investigator

Date:

Signature:

**DATA PROVIDER:**

By:

Title:

Date:

Signature:

**EXHIBIT “A”**

**Protocol (attached)**

**EXHIBIT “B”**

**Data Dictionary Codebook (attached)**