COVID-NL Policy for Access to and Sharing of COVID-19 Data

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This COVID-NL Policy for Access and Sharing of COVID-19 Data ("Policy") is intended to support the rapid and efficient secondary use of COVID-19 related data collected by the collaborating Dutch healthcare providers ("Partners") while respecting applicable law, regulations and ethical principles. These data typically have been collected in the context of clinical care and made available for observational studies while being harmonized across the participating institutions ("Partners") creating a national COVID-19 registry under the name COVID-NL.

This Policy for data sharing assumes that each Partner has verified that there is an appropriate legal basis in accordance with the GDPR and WGBO for the provision of the Data to Researchers.

The re-use of Data regulated under this Policy is targeted to Researchers which are located within the European Economic Area, and requires the involvement of at least one of the Partners in executing the Study. Data sharing to other scientists will require additional provisions outside the remit of this Policy.

The Policy follows a generic data sharing and request procedure where meta data corresponding to the Data are publicly advertised in the national COVID-NL portal, and requests can be processed through a workflow tool called Podium.

An important aspect of the process outlined in this Policy is the presence of a national Data Access Committee (DAC), which will be implemented to evaluate the scientific relevance of the data request, and to identify the potential for synergy between research proposals. The final legal evaluation whether to participate in Data requests is a local responsibility for each of the Partners to be evaluated individually after the DAC has approved the request.

This Policy is intended to be used in conjunction with the “COVID-NL Register (and Biobank Policy) Regulatory Document".
Main updates in version 2.0
- The link to the Regulatory Document has been established and terminology is aligned between the two documents.
- The need for a Data Sharing Agreement for Data deliveries between Partners has been removed.
- The Investigational Research Board has been removed from the workflow and replaced by a local legal review.
- The request and approval workflow has been updated to the one that is being implemented.

Acknowledgements
The present Policy is compiled by reusing and merging procedures and processes from a number of existing policies and templates:

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1. INTRODUCTION

The COVID-19 pandemic raises a whole range of new research questions regarding optimal prevention, diagnostics and treatment of the disease, as well as for control of new virus outbreaks. The urgent societal need to address these questions prompted the Dutch research community to initiate many observational studies, mostly based on data collected from clinical practice and routine diagnostics. While data sharing amongst researchers and health care practitioners is a generic requirement for a learning healthcare system across all disease areas, this is even more relevant for COVID-19. Sharing the resulting data sets across the broader COVID-19 research community is essential for rapid progress in disease prevention, diagnosis and treatment, but at the same time requires great care to protect the rights and the privacy of the patients involved.

Sharing of health data is already an integral part of current medical care and research. The present data access policy (hereinafter referred to as 'Policy') builds on this practice and provides a standard data access procedure for observational clinical Data collected for the COVID-NL Register (further detailed in Annex 3 to this Policy), which is further supported by an efficient Data request procedure and a corresponding Regulatory Document for Data sharing. This way, legitimate Data access requests can be processed efficiently as required for progress in COVID-19 research with full protection of the patients’ rights.

This access Policy presents three areas of guidance:

i) ethical principles
ii) governance procedures
iii) practical procedures for access

These three areas provide the ethical and legal framework and practical procedures to guide access to Data.

2. DEFINITION OF TERMS

Capitalized terms not defined in this list of definitions shall have the meaning as defined in the Regulatory Document.

Bona fide researcher
A Researcher with:
1. an intention to generate new knowledge and understanding using rigorous scientific methods;
2. an intention to publish the research findings in the scientific community, without restrictions other than IP and data protection, and with minimal delay, for wider scientific and eventual public benefit; and where intended activities are consistent with legal and ethical requirements.

**Confidential information**
All information, know-how, grant applications, method of work, techniques, expertise of Partners regarding the Data, its characteristics and Partners' research concerning the Data, whether of a scientific, technical, engineering, operational, or economic nature, supplied to or obtained by the Researcher in written form, in the form of drawings or in the recording of oral conversation, or samples.

**Data sharing agreement**
A signed contract between the Researcher and the Partners specifying additional conditions under which the Data are made available by the Partners to the Researcher.

**Data access committee (DAC)**
A national body of named individuals installed jointly by the Partners that advises the Partners about Data release to Researchers based on the principles outlined in this Policy, the Regulatory Document, and applicable law and regulations.

**GDPR**
The Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and on the free movement of such data (General Data Protection Regulation).

**Personal data**
Any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (GDPR Article 4.1).

**Project outcome**
Research papers, abstracts, presentations, inventions, patents, software, new therapies, and other types of commonly acknowledged medical research achievements. This also includes a report on the use of Samples and/or Data.

**Pseudonymisation**
The processing of Personal Data in such a manner that the Personal Data can no longer be attributed to a specific data Subject without the use of additional information, provided that such additional information is kept separately and is
subject to technical and organizational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person (GDPR Article 4.5).

Subject
A person from whom the Data was obtained.

WGBO
“Wet op de geneeskundige behandelovereenkomst” (WGBO), the Dutch Medical Treatment Agreement Act.

3. LEGAL PREMISE

Partners warrant that they:

a) have verified that there is an appropriate legal ground for the provision of the Data to the Researcher in accordance with the WGBO (specifically articles 7:458 and 7:467 BW) and GDPR (such as Article 6 and/or 5.1 sub b GDPR);

b) that the Subjects will be notified about ongoing research;

c) that there is a valid exception to the prohibition for processing personal health data (Article 9 GDPR);

d) that Data are provided under approval from the relevant (ethics) committee to the extent required.

4. GOVERNING ETHICAL PRINCIPLES

Access to Data is supported according to the following principles:

A. Scientific integrity: Partners are expected to act in an honest and transparent manner and uphold the highest standards of quality in scientific research.

B. Respect for responsible governance regarding data: Partners are expected to take the necessary precautions and safeguards to avoid data breaches. This entails protecting the Data and putting in place state-of-the-art safety measures for data security.

C. If the Researcher despite the necessary precautions and safeguards becomes aware of a Personal Data breach, the Researcher will take further action according to the process detailed in the Regulatory Document with the support of the Coordinator and the Partners involved where required to inform the Data Subjects involved.

D. Respect for intellectual property: Sharing of Data needs to be performed in a way that protects intellectual property rights of the parties involved. It also needs to address the requirements of institutions and third-party funders.

E. Equity and inclusivity of users: Bona Fide Researchers who meet the relevant criteria should be granted access based on fair and non-discriminatory terms.

F. Reciprocity: Research also implies giving something back. Feedback regarding general results should be channeled towards institutions and the patient community (subject to ethical and legal constraints).
G. Transparency: Partners shall treat all access requests respectfully and will only use information obtained from those requests for further research after consultation of the Researcher.

H. Collaboration: COVID-19 research requires collaboration to arrive at national consensus; data requests, results, and new data sets will therefore be shared as openly as possible.

I. Scientific quality: the urgency to deal with public health issues raised by the COVID-19 pandemic should not compromise general principles of good scientific practice; the results published should be reliable and verifiable.

5. PROCEDURES GOVERNING ACCESS TO AND USE OF DATA

A. Further use of the Data next to the Researcher’s Study shall remain under the control of the Partner providing the Data, unless otherwise specified in a separate agreement.

B. Researchers will be required to follow the request procedure for Data (see Section 6).

C. Partners collaborate in the COVID-NL network of COVID-19 research institutions. Partners have mandated a national Data Access Committee (DAC) installed by that network to evaluate the scientific aspects of Data requests, advising Partners to approve or reject the request. The composition of this DAC is outlined in Annex 1 to this Policy.

D. Partners have implemented a local process to evaluate the local and legal aspects of the Data request on behalf of the Partner. Each Partner has the right to decide on its own discretion whether to participate in a Data request after the approval of the DAC.

E. Partners and the Researcher jointly agree on the way to access or transfer the Data. At all times, data access or transfer should use a secure and reliable connection.

F. If the Data is transferred, then the Partner employing the Researcher needs to guarantee that the Data are stored in a secure and operational facility accompanied by an appropriate access policy.

G. Data will in principle be used for research in the public interest. Subject to provisions in the patient consent (if any), Partners may agree that Data may be used for "for-profit" research. This may lead to specific requirements regarding the use of the Data to be established specifically in a Data Sharing Agreement.

H. Permitted usage and limitations regarding the Data are specified in the Regulatory Document.

I. The implementation of these procedures and possible revisions thereof are overseen by the Steering Committee as defined in the Regulatory Document. The composition of the Steering Committee is defined in Annex 2 to the current Policy document.
6. REQUEST PROCEDURE FOR ACCESS TO DATA

The request procedure for accessing Data comprises the following steps:

**Step 1: Data selection**
The Researcher selects the Data to be requested, preferably in the national COVID-19 portal where the Partners have published meta data for data sets available for request. The portal offers a specific data request functionality ("Podium") to further streamline the data request process. The identity of the Researcher and his/her (Partner) institute will be verified by registration in the Podium application offered through the portal. The DAC will only consider Data requests after the identity has been confirmed.

**Step 2: Internal review of request**
The Researcher follows internal procedures of the own Partner institute to ensure support for the intended Study requiring the Data request.

**Step 3: Request of Data**
The Researcher files a request for access to Data via Podium. The specific request form within Podium capturing the Study Proposal must be filled in. When submitting the Data request in Podium, the Researcher has to acknowledge that he/she read and understood the main principles for usage of the Data (based on a summary of Section 3 and 4 of this document).

**Step 4: National review of the request**
The national DAC will process the request in compliance with the governing ethical principles (Section 4 of this Policy) and the regulations outlined in the Regulatory Document. The DAC will assess the application on content, scientific rigour, and feasibility. The DAC may request refinement of the request. The DAC may also encourage multiple Researchers to collaborate when research proposals are similar.
or recommend a Researcher to seek collaborators in multiple institutions. After receiving feedback from the DAC, the Researcher follows up promptly with the DAC in order to provide any additional information needed to assess whether access can be granted.

**Step 5: Local review of the request**

Each Partner must comply with the governing ethical principles (Section 4 of this Policy) and the regulatory conditions, in particular GDPR and WGBO (e.g., data protection regulations, assessment of compliance of informed consent with the approved/proposed project, assess whether the amount of extraditable data required is justified). Based on these considerations, each Partner will decide individually whether the Data can be released for the project requested. The Partners will usually not re-evaluate the scientific aspects of the request.

**Step 6-7: Data is made available**

The Researcher will be either given direct access to the Data to execute the Study, or the Data may be transferred to the Researcher’s institute to execute the study locally within the Research’s institute.

**Step 8: Study completion**

After request completion, the Partners may publish the approved research question(s) on the national COVID-19 data portal or similar websites. The Researcher is expected to report the analysis outcomes relevant to the outbreak as soon as results become available.

### 7. PUBLICATION AND AUTHORSHIP

A. Each Partner shall always be free to use their own Data for their own internal teaching, research, educational, clinical and publication purposes under their own title.

B. Authorship of any publications shall follow the principles set out in the ICMJE recommendations 'Defining the Role of Authors and Contributors' as can be found on [www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html](http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)

C. It is recommended to publish results under a multi-author group, e.g. the COVID-NL research coalition, in order to credit the contributions of all Partners. When submitting the manuscript, the corresponding author should specify the group members who can take credit for the work as authors, as well as who should be listed as contributors or be acknowledged. There will be no joint authorship roles.

D. Researcher will enable the DAC to perform a (lightweight) review of publications before submission.

E. In every disclosure by the Researcher, based upon the study results, the Researcher shall appropriately acknowledge the Partners as contributors of the Data.
8. OPEN ACCESS

Since COVID-19 is a public health emergency of international concern, there is a need for Researchers to make any information available that might have value in combatting the crisis. The Partners therefore require Researchers to make the results arising from Data publicly available, subject to IP and data protection constraints. The Researcher is required to make all peer-reviewed research publications relevant to COVID-NL open access, or freely available with clear statements regarding the availability of underlying data.
ANNEXES
ANNEX 1 – MEMBERS OF THE DATA ACCESS COMMITTEE

- Prof. Dr. W.J. Wiersinga, Amsterdamumc
- Prof. Dr. M.A. Ikram, ErasmusMC
- Dr. M.S. Arbous, LUMC
- Prof. Dr. C.D.A. Stehouwer, MUMC+
- Prof. Dr. F.L. van de Veerdonk, Radboudumc
- Prof. Dr. G.H. Koppelman, UMCG
- Dr. C.H.E. Boel, UMCU
ANNEX 2 – MEMBERS OF THE STEERING COMMITTEE

- Representing Amsterdamumc: Prof. Dr. M.J.A.P. Daemen
- Representing ErasmusMC: Prof. Dr. J.G.J.V. Aerts
- Representing LUMC: Prof. Dr. F.R. Rosendaal
- Representing MUMC+: Prof. Dr. J.E. Wildberger
- Representing Radboudumc: Prof. Dr. C.B. Roes, deputy Dr. P. Manders
- Representing UMCG: Prof. Dr. H.W.G.M. Boddeke
- Representing UMCU: Prof. Dr. M.J.M. Bonten
ANNEX 3 – DATA COLLECTED IN THE COVID-NL REGISTER

Data collected from Donors participating in COVID-NL:
• Pseudonymized observational health data about COVID-19 disease status and recovery according to the CORE ISARIC COVID-19 data dictionary v 27 August 2020 (most Partners) or the RAPID ISARIC COVID-19 data dictionary v 1 September 2020 (LUMC). See also: isaric.org/research/covid-19-clinical-research-resources/.

Data collected from researchers requesting data from COVID-NL or researchers considering to request data:
• Name, e-mail address, and affiliation (not pseudonymized)