Rijksinstituut voor Volksgezondheid
en Milieu
Ministerie van Volksgezondheid,
Welzijn en Sport

Dutch National Institute for Public Health and the Environment (RIVM)
(*Rijksinstituut voor Volksgezondheid en Milieu*)
Dutch Ministry of Health, Welfare and Sport

Model Data Sharing Agreement (DSA)

FOR NON-COMMERCIAL RESEARCH PURPOSES WITHIN THE EU

(RIVM = data provider)

This template always needs to be aligned with the actual situation in which the Data is provided. Approval of the final version of this data sharing agreement by the privacy officer RIVM is required.

DATA SHARING AGREEMENT

FOR NON-COMMERCIAL RESEARCH PURPOSES

The undersigned:

1. The State of the Netherlands, having its seat in The Hague, the Netherlands, represented by its Minister of Health, Welfare and Sport, on behalf of the Minister represented by 5.1.2e 5.1.2e 5.1.2e, 5.1.2e (Rijksinstituut voor Volksgezondheid en Milieu) (RIVM), on behalf of him 5.1.2e 5.1.2e 5.1.2e, 5.1.2e having its home office at Antonie van Leeuwenhoeklaan 9, 3721 MA Bilthoven, the Netherlands, hereinafter referred to as the 'Data Provider' or 'RIVM';

   and

2. 5.1.2e 5.1.2e, University Medical Center Utrecht, having its registered office in Utrecht, The Netherlands, situated at Heidelberglaan 100, 3584CX, Utrecht, The Netherlands, for these purposes of this Agreement legally represented by

   5.1.2e 5.1.2e, 5.1.2e Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Heidelberglaan 100, 3584CX Utrecht, The Netherlands

   5.1.2e, 5.1.2e, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Heidelberglaan 100, 3584CX Utrecht, The Netherlands

   5.1.2e Dept. of Econometrics and OR, Tilburg University, Warandelaan 2, 5037AB, Tilburg, The Netherlands

   hereinafter referred to as 'User';

each, individually, a "**Party**" and collectively, the "**Parties**".

Recitals:

A. Parties have considerable experience in the field of infectious disease epidemiological research and mathematical modeling;

   5.1.2e 5.1.2e, was 5.1.2e in many large-scale epidemiologic studies and 5.1.2e randomized trials of prevention and treatment of infectious diseases, and closely collaborates with the mathematical modelling team of the UMC Utrecht. This research question fits in the larger scope of modelling studies to inform national policy makers (e.g., [1], [2], [3]).

   5.1.2e main expertise is infectious disease modelling. During the COVID-19 pandemic she has made important contributions for evaluating the impact of government-imposed interventions and self-imposed prevention measures [2], digital and traditional contact tracing strategies [1] and school- and non-school-related measures [3]. This proposal

is part of her main line of research.

5.1.2e main research is in time series econometrics and statistics, dynamic modelling over long periods of time, and quantifying the effects of national policies in the short- and long-run. Because her main research has focused in evaluating national policy changes, both the statistical techniques and the modelling she previously used are also those used in the mathematical modelling of disease spread. She received a Tilburg University grant to address the impact of national Dutch policies on the regional spread of COVID-19, and therefore this proposal is part of her main line of current research.

1] Teslya A, Pham TM, Godijk NG, Kretzschmar ME, Bootsma MCJ, 5.1.2e. Impact of self-imposed prevention measures and short-term government-imposed social distancing on mitigating and delaying a COVID-19 epidemic: A modelling study. *PLOS Medicine*. 2020;17(7):1-21. doi:10.1371/journal.pmed.1003166.

[2] Kretzschmar ME, 5.1.2e, Bootsma MCJ, van Boven M, van de Wijgert JHHM, 5.1.2e MJM. Impact of delays on effectiveness of contact tracing strategies for COVID-19: a modelling study. *Lancet Public Health.* 2020 Aug; 5(8):e452-e459. doi: 10.1016/S2468-2667(20)30157-2.

[3] 5.1.2e, van Dorp CH, 5.1.2e 5.1.2e MCJ, van de Wijgert JHHM, 5.1.2e MJM, Kretzschmar, ME. (2021). Model-based evaluation of school- and non-school-related measures to control the COVID-19 pandemic, *Nature Communications. 2021;* 12: 1614. doi: 10.1038/s41467-021-21899-6

B. User performs data analysis for the non-commercial research entitled ,
The role of undocumented and documented infections among children and adults in national and regional transmission of SARS-CoV-2

Regular universal screening for SARS-CoV-2 infection during the vaccination rollout

[Protocol and description attached in Appendix A]

hereafter the "**Study**"); and

C. As a service to the research community, Data Provider wishes to disclose or make available to User certain Data (as defined below) collected in a research already conducted by Data Provider, and User 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 and all applicable laws and regulations.

Therefore the parties hereby agreed that:

1. Definitions

The words or formulations used in this Data Sharing Agreement shall have the following meaning in both singular and plural:

- **Appendix:** the appendices to this Agreement, which are inextricably linked to it
- **Agreement:** this Data Sharing Agreement between User and the Data Provider
- **Data:** Data in the sense of data collection
- **GDPR:** the abbreviation GDPR stands for General Data Protection Regulation (EU 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data)
- **Permitted Purpose:** to conduct the Study and to publish the results of the Study solely for the in this Agreement agreed purpose

2. Disclosure and scope of Data

2.1 Subject to the terms and conditions of this Agreement, Data Provider will disclose to User certain data as described in Appendix B attached hereto ("**Data**").

2.2 User acknowledges that the Data is provided on an "as is" basis without any warranty of satisfactory quality or fitness for a particular purpose or use, or any other warranty, express or implied.

2.3 Data Provider agrees to disclose the Data to User solely for the Permitted Purpose.

2.4 Data Provider shall only provide such Data as necessary for the Study.

3. Data Protection

3.1 Data Provider will ensure that all Data has been obtained in accordance with applicable international and national laws, statutes, guidelines and regulations from research conducted in compliance with sound scientific methods and principles and that it is authorized to provide the Data.

3.2 User warrants that all work using the Data will be carried out in compliance with all applicable laws. regulations, guidelines, best practices and approvals.

3.3 User will not perform any act which would lead to the re-identification of the individuals concerned, including by linking different sets of data, comparing and processing data.

3.4 Upon Data Provider's first request, User 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.

3.5 User shall not attempt to contact any data subject.

3.6 User shall take reasonable steps to delete data for a given subject when the Data Provider deems that a subject has withdrawn his or her consent. User confirms that it will deal promptly and appropriately with any withdrawals by a data subject of which the Provider notifies to User.

3.7 User shall take appropriate technical and organisational measures to safeguard a level of security attuned to the risk, so that the use of the provided Data complies with the requirements under the EU Data Protection laws and other Applicable Legislation and Regulations concerning the Processing of Personal Data, and the protection of the rights of

Data Subjects is safeguarded.

3.8 User shall ensure that all employees, agents, and 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. User 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.

3.9 User agrees not to give access to data, in whole or part, or any identifiable data derived from the data, to any third party. Nor is it permitted to transfer the Data, as made available to the User, to (unknown) third parties without the consent of the Data Provider.

3.10 User shall notify Data Provider without unreasonable delay after discovery of a Data Breach or a reasonable suspicion of a Data Breach.

3.11 On the Completion of the Research Project or on the termination of this agreement, User will delete the data and confirm to the Data Provider in writing that this has taken place.

3.12 Any provisions of this agreement intended to protect the rights of human data subjects shall survive the expiry or termination of this Agreement.

4. Intellectual Property Rights

4.1 Title to the Data is and remains in the ownership of the Data Provider and the Data are made available to User as a service to the research community.

4.2 User shall be entitled to any inventions to the extent that these result from his own independent use of the Data. He shall grant the Data Provider a worldwide non-exclusive royalty-free irrevocable research license with respect to any such inventions. If User elects not to seek any intellectual property protection with respect to such inventions he shall transfer any such rights to the Data Provider at no cost.

4.3 To the extent that the Data Provider and the User have each contributed to an invention with respect to the Data, they shall jointly own any rights to such an invention. Inventions made solely by the employees or agents of one party shall be owned by that party.

4.4 Except as expressly set forth in this clause, nothing herein shall be deemed to grant to either the Data Provider or User any rights under the other party's patents, patent applications, trademarks, copyrights, trade secrets, know how (whether patentable or unpatentable) or other intellectual property rights.

5. Third parties

This Agreement will be binding upon and inure to the benefit of the respective successors and assignees of the Parties hereto. However, User may not assign or delegate its rights or obligations under this Agreement, in whole or in part, without the prior written consent of the Data Provider.

6. Termination and effects of termination

6.1 This Agreement shall expire after the User has finalized processing of the provided data, which is expected not to be earlier than 31 December 2021, unless earlier terminated by the mutual written agreement of the Parties.

6.2 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 twenty (20) days after notice from the aggrieved Party demanding such remedy.

6.3 Upon termination of this Agreement, User shall, upon the written request of Data Provider, either return or destroy all Data received from Data Provider, and User shall not retain any copies of such Data; provided, however, that Data may be retained for continued use by User 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, User or (ii) is necessary to comply with all applicable laws and regulations as well as User'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.

6.4 Any clauses which will be expected or intended by its nature to survive the termination or the expiration of this Agreement, shall survive the termination or the expiration of this Agreement.

6.5 The confidentiality rights and obligations and the transfer of the data to third parties 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.

7. Liability

7.1 User will indemnify the Data Provider against all losses (whether direct or indirect, reasonably foreseeable or specifically contemplated by the Parties), damages, costs, expenses (including but not limited to reasonable legal costs and expenses) that it incurs as a result of: (i) the use, storage or disposal of the provided Data; or (ii) any negligence or wilful default of the User, provided that the Data Provider agrees to use its reasonable endeavours to mitigate any loss.

7.2 Both Parties acknowledge and agree that the date is being supplied with no warranties, express or implied, and Data Provider expressly disclaims any warranty of merchantability, fitness for a particular purpose. Data Provider makes no representation that the use of the Data will not infringe the patent or proprietary rights of any third party.

8. Alterations

This Agreement reflects the entire Agreement between Data Provider and User. Changes or additions to this Agreement shall only come into effect after mutual agreement thereon has been confirmed in writing.

9. Applicable law and jurisdiction

This Agreement will be governed by and construed in accordance with the laws of the Netherlands; parties agree that the competent courts of Midden-Nederland, location Utrecht, will have exclusive jurisdiction over any suit, action, proceedings or dispute arising out of, or in connection with, this Agreement.

Executed by the Parties:

Agreed and executed in two-fold,

In Bilthoven, 30 April 2021	In Utrecht, 5 April 2021
5.1.2e	On behalf of User
5.1.2e	5.1.2e
5.1.2e	5 5.1.2e
5.1.2e	5.1.2e

Appendices:

APPENDIX "A"

PROTOCOL / STUDY DESCRIPTION

I. Description of the research project or otherwise purpose for which the transferred data or physical material will be used.

The role of undocumented and documented infections among children and adults in national and regional transmission of SARS-CoV-2

The literature on the role of younger and older children in SARS-CoV-2 in the transmission of SARS-CoV-2 is vast, spanning different countries and different time periods during this pandemic, and a comprehensive summary, also on evidence from the Netherlands, can be found in [4]. The role of children in transmission is assessed through various methodological approaches: measuring mean duration of viral shedding, random samples of the population, household studies, contact-tracing studies in clusters of infections, and data-driven epidemiological modelling at national scale per age category. Our study belongs to the category of data-driven stochastic epidemiological studies at national scale, and this approach is motivated, as in [3] and [5-11], by the lack of systematic high-frequency data that would allow one to disentangle the role of children and schools at different stages of the pandemic from other confounding factors such as non-pharmaceutical interventions (NPIs) for the rest of the population.

There is a general consensus that while children of all ages can transmit the virus, younger children are less susceptible to the virus and they are less likely to be hospitalized – [3-4]. Despite this evidence, school closures persisted throughout the first and second wave in some countries, possibly due to the lack of understanding of the role of elementary and secondary schools in transmission over long periods of time, when other measures are introduced or relaxed.

Netherlands is one of the few countries that strived to keep (elementary) schools open as much as possible, and therefore provides an ideal ground to study the effect of transmission in children and schools both when community rate transmissions are high and when they are low. Despite this, there are very few publicly available papers on the role of children and schools with Dutch data – [3], [12], and there is no large scale study for Netherlands that makes use of infection or hospitalization data from both the first and the second wave.

The most important difficulties in accurately quantifying the effect of school closures and openings on regional infections and hospitalization rates in the Netherlands over longer periods of time are: a) scarce testing of younger children, which leads to difficulties in quantifying in real-time the effect of transmission of undocumented infected children to other children and the rest of the population; b) the need to model other NPIs imposed by the government, and compliance with them; c) lack of reliable and freely available daily regional hospitalization data after June 1, per age categories.

In this project, we address a) and b) directly using freely available daily RIVM data on documented infected across regions (provinces; 'veiligheidsregios') and age groups from the beginning of the pandemic until recent periods. We develop a spatial SEIR model of infections across regions, where undocumented infected are modelled jointly with documented infected, assumed more mobile that the latter, and identified through mobility data across provinces. Children are less mobile across provinces, and the undocumented infected children are identified through their co-movement with documented infected children, as well as total infected from the other age compartments. Since the model is compartmentalized not only by province, but also by age, we estimate time-varying transmission coefficients within and across age groups using contact matrices from [13] and freely available Google mobility data to proxy the effect of government measures as well as compliance with those measures.

The additional values of this project compared to the current literature is we can accurately quantify the effect of school and non-school measures on infections and hospitalization *per age group and per region* in the Netherlands over long periods of time, allowing hospitals to plan better their capacity when measures are introduced/relaxed, and for future pandemics.

But, to do so, we need c), reliable daily new hospitalization data per age-group and region over the course of the entire pandemic; without this data, it is very difficult to give an accurate quantification of the impact of different measures on hospitalization rates. We would only be able to quantify the effects of school and non-school measures on infections, which is not directly useful to hospitals in planning their capacity. Note that ICU data will not help, because our analysis is daily, and the number of children in ICUs has been too low to identify the rate of hospitalizations per age category.

Regular universal screening for SARS-CoV-2 infection during the vaccination rollout

We also intend to use the age-stratified hospitalization data to access the prospects of reopening of society by regular universal screening for SARS-CoV-2 infection during the vaccination rollout. Our first results on this topic are available from the preprint [14]. In future research, for which the data are requested, we would like to extend the mathematical model in [14] to include age stratification and fit it formally to age-specific hospitalization data.

References (first three references are repeated from above for readers' convenience):

[1] Teslya A, Pham TM, Godijk NG, Kretzschmar ME, Bootsma MCJ, 5.1.2e. Impact of self-imposed prevention measures and short-term government-imposed social distancing on mitigating and delaying a COVID-19 epidemic: A modelling study. *PLOS Medicine*. 2020; 17(7):1-21. doi:10.1371/journal.pmed.1003166.

[2] Kretzschmar ME, 5.1.2e, Bootsma MCJ, van Boven M, van de Wijgert JHHM, 5.1.2e MJM. Impact of delays on effectiveness of contact tracing strategies for COVID-19: a modelling study. *Lancet Public Health.* 2020 Aug; 5(8):e452-e459. doi: 10.1016/S2468-2667(20)30157-2.

[3] 5.1.2e, van Dorp CH, 5.1.2e, 5.1.2e MCJ, van de Wijgert JHHM,

5.1.2e MJM, Kretzschmar, ME. (2021). Model-based evaluation of school- and non-school-related measures to control the COVID-19 pandemic, *Nature Communications. 2021;* 12: 1614. doi: 10.1038/s41467-021-21899-6

[4] ECDC. COVID-19 in children and the role of school settings in transmission - first update. (2020 Dec). https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-in-children-and-the-role-of-school-settings-in-transmission-first-update_1.pdf

[5] Prem K, 5.1.2e, Russell T, Kucharski A, Eggo R, Davies N, et al. The effect of control strategies to reduce social mixing on outcomes of the COVID-19 epidemic in Wuhan, China: a modelling study. *Lancet Public Health.* 2020;5(5):e261-e270. doi:10.1016/S2468-2667(20)30073-6.

[6] Davies NG, Klepac P, 5.1.2e, Prem K, Jit M, Pearson CAB, et al. Age-dependent effects in the transmission and control of COVID-19 epidemics. *Nature Medicine.* 2020;26(8):1205-1211. doi:10.1038/s41591-020-0962-9.

[7] Davies NG, Kucharski AJ, Eggo RM, Gimma A, Edmunds WJ, Jombart T, et al. Effects of non-pharmaceutical interventions on COVID-19 cases, deaths, and demand for hospital services in the UK: a modelling study. *The Lancet Public Health.* 2020 Jul; 5(7):e375-e385. doi: 10.1016/S2468-2667(20)30133-X.

[8] Dehning J, Zierenberg J, Spitzner FP, Wibral M, Neto JP, Wilczek M, et al. Inferring change points in the spread of COVID-19 reveals the effectiveness of interventions. *Science.* 2020;369(6500). doi:10.1126/science.abb9789.

[9] Giordano G, Blanchini F, Bruno R, Colaneri P, Di Filippo A, Di Matteo A, et al. Modelling the COVID-epidemic and implementation of population-wide interventions in Italy. *Nature Medicine.* 2020;26:855-860. doi:10.1038/s41591-020-0883-7.

[10] Gatto M, Bertuzzo E, Mari L, Miccoli S, Carraro L, Casagrandi R, et al. Spread and dynamics of the COVID-19 epidemic in Italy: Effects of emergency containment measures. *Proceedings of the National Academy of Sciences.* 2020; 117(19):10484-10491. doi:10.1073/pnas.2004978117.

[11] Bertuzzo E, Mari L, Pasetto D, Miccoli S, Casagrandi R, Gatto M, et al. The geography of COVID-19 spread in Italy and implications for the relaxation of confinement measures. *Nature Communications.* 2020;11(1):4264. doi:10.1038/s41467-020-18050-2.

[12] Li R, Pei S, Chen, B, Song Y, Zhang T, Yang W, Shaman J. Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV-2), *Science.* 2020; 368(6490):489-493, doi: 10.1126/science.abb3221.

[13] Backer JA, Mollema 5.1.2e RAE, Klinkenberg D, van der Klis FRM, de Melker HE, van den Hof S, Wallinga J (2020). The impact of physical distancing measures against COVID-19 transmission on contacts and mixing patterns in the Netherlands: repeated cross-sectional surveys in 2016/2017, April 2020 and June 2020. 2020. https://www.medrxiv.org/content/10.1101/2020.05.18.20101501v2

[14] Regular universal screening for SARS-CoV-2 infection may not allow reopening of society after controlling a pandemic wave. MCJ Bootsma, ME Kretzschmar, G Rozhnova, JAP Heesterbeek, JAJW Kluytmans, MJM 5.1.2e medRxiv 2020.11.18.20233122; doi: https://doi.org/10.1101/2020.11.18.20233122

APPENDIX "B"

DISCLOSED DATA; The processing of personal data

Data to be disclosed by RIVM to User

The number of people hospitalized daily, from Feb 27, 2020 until the most recent period available, per FIRST date of admission into hospital, broken down as follows:

- per age of hospitalized patient –in age bins : 1) ages [0,10), [10,20), [20,30), ..., [80,90), [90+) and 2) separately the age bins [0,4), [4,12), [12,18), and the rest of the population.
- per province (not the location of admission, but residency of the patient).

Note that we do not need the duration of stay in the hospital, the date of discharge, or any information about movement across hospitals, because we are only modelling new hospitalizations.

APPENDIX "C"

Appropriate technical and organizational measures

This annex must specify the standards and measures that the User must apply or take in connection with the security of the Processing. For this, reference can be made to documents in which standards and measures are laid down, such as, where appropriate, the program of requirements or the request for quotation.

Note: this appendix is filled in by the User and checked by information security!

The User gives at least a description of:
1. the measures taken to ensure that only authorized personnel has access to the Personal Data.
2. the measures taken to protect Personal Data against accidental or unlawful destruction, accidental loss or alteration, unauthorized or unlawful storage, Processing, access or disclosure.
the measures taken to identify weaknesses with regard to the Processing of Personal Data in the systems used to provide services to Data Provider/ RIVM.

All data will be stored in the secured Research Folder Structure (RFS) of the UMC Utrecht. Adequate access and control rights are in place to guarantee that data can only be accessed by authorized personnel. The RFS follows GCP guidelines for research data integrity with respect to the treatment of personal data by the implementation of differentiated access rights on folders with and without privacy information. Direct identifiable personal data is always stored separately from other research data. Researchers doing the analysis only have access to pseudonymized data and personal data can be accessed by authorized staff only. Backups from all stored data on the secured RFS are made automatically twice a day by the central IT department. Data will never be stored on personal laptops, USB drives or any other portable drives to avoid that data will be lost or stolen.

Formal procedures are in place to report all cases of data breaches as soon as possible to the privacy team of the UMCU. The privacy team then assesses the potential impact of the incident. They check, for example, whether the information in question is of sensitive nature and whether the data breach can lead to serious consequences for those involved. This privacy team includes: the data protection officer, the senior information security adviser and an IT specialist from the central IT department. Based on the advice of the senior information security adviser and the ICT specialist, the data protection officer determines whether the incident must be reported to the Dutch Data Protection Authority. If this is the case and as soon as a report is made to the Dutch Data Protection Authority, RIVM will also be informed. The UMC Utrecht applies the premise that there is only a data breach if the leak is outside the sphere of influence of UMC Utrecht. A data breach within the sphere of influence of UMC Utrecht is protected by the duty of confidentiality, for example: an internal e-mail with personal data to the wrong colleague at UMC Utrecht.