



Confidentiality and Due Diligence Agreement for participation
in the HEVnet system

Datum
17 June 2019

The Hepatitis-E Network is a multidisciplinary group of European HEV experts. HEVnet is the data repository system of the Network, coordinated by RIVM, The Netherlands. The Network consists of virologists, epidemiologists, clinicians and other public health or veterinary professionals as well as academic researchers, who are involved in the genotyping of HEV and its application, to promote public health. They are willing to share data along with relevant background information, where available, for international molecular surveillance and infectious disease control.

The HEVnet system, on which this Agreement sees, is the ensemble of a data repository and the HEVnet software platform of tools, algorithms, models and bioinformatic methods, making it possible for end users to run analyses for inter alia diagnostics, phylogeography, phylodynamics and the mapping of transmission of Hepatitis E.

The establishment of the HEVnet repository system has the following objectives:

1. To enable monitoring and surveillance of European health trends, including mapping of population structure of HEV strains and cluster investigation
2. To support outbreak investigations, source attribution and analytical studies
3. To facilitate epidemiological and clinical studies which aim to identify risk factors, improve understanding of the burden of HEV and support interventions.

Within HEVnet privileged information will be exchanged in a protected working space by the contributors. Therefore, participation in the HEVnet involves the signing of this Confidentiality Agreement. Additionally, participants can and will be using other participant's/contributor's data for their analyses and for publications. Therefore, participation in HEVnet involves the signing of a code of conduct as part of this Agreement.

Compliant to public European policies and as a principle of the promotion of research for the public's health, all data submitted to HEVnet will finally become

publicly available after a fixed period of time and taking into account the privacy protecting procedures elaborated in this Agreement. A curating body is installed that will, inter alia, oversee these procedures.

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- The hosting organization RIVM acts qualitate qua as Curator of HEVnet. The task of the Curator is to oversee the content-wise good functioning of HEVnet, to protect the integrity and continuity of the HEVnet system, including, but not limited to, the compliance to this Agreement.
- The Curator is accountable to the Curator group, which is selected from the participants in HEVnet.

Therefore, Submitting Parties and Users of data must sign this Agreement prior to gaining access to the protected working space in the HEVnet system.

By signing this Agreement, the Submitting Parties and User (further: Participants) agree to the following:

- a. Participation in HEVnet goes under the 'quid pro quo' principle. This means that access to the protected working space and the use of data is open to parties who submit their own data. Exemptions are at the discretion of the Curating group.
- b. It is the responsibility of the Submitting Party that the submission of data is done in accordance with the applicable laws and regulations of the European Union and of the country of origin. If the special situation arises that person-identifying data are submitted in the HEVnet protected working space, the Submitting Party declares that these data are obtained and shared in accordance to the EU General Data Protection Regulation and the complementary domestic regulations. A joint controller, processor and data-leak agreement will be undersigned.
- c. All data submitted to the HEVnet system, having not already been made available to the public domain, will be regarded as confidential and are submitted under retention of ownership of the Submitting Party. If ownership rights belong to a third party, the Submitting Party shall be deemed to rightfully act on behalf of this party.

Without prejudice to the special situation described in article (i), Participants in HEVnet declare not to share other participant's data, including electronic copies, hard copies and screen dumps of the system, with institutions or persons not participating in HEVnet and not having signed this Agreement, without written consent proving incontrovertible permission.

d. The data provider and the submitting party will not be held liable for the fitness to use, faults or errors in the data.

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e. All (sequence) data submitted to the HEVnet protected working space will become publicly available at a time specified by the data provider, but no later than 18 months after submission. The data will be stripped of all person-identifying (if applicable) and otherwise sensitive meta-data before bringing into the public domain. To this end a Curator is appointed who bears responsibility to the Submitting Party and is accountable to the Curator group of HEVnet

f. No data in the protected working space will be used for publication without written consent and proper acknowledgement of the submitting party. As a standard attitude, due diligence shall be exercised by each User to inform submitting parties timely on the intended use of their data.

g. In case of a detection or suspicion of a public health threat it is, in accordance with their national law, the responsibility of the data provider to notify the relevant authorities. A User or group of collaborating Users of HEVnet-data that detects or suspects such threat shall inform without delay the Submitting Party(s) of their findings.

h. In case of detection or suspicion of a cross border public health threat, the User or group of collaborating Users of HEVnet-data that detects or suspects such threat, shall inform the Submitting Parties of the countries of concern, including the information that Users will notify the relevant authorities of their own countries if they are involved. In such a case Submitting Parties hereby declare to agree that all necessary data will be provided by Users to their health authorities, clearly marked confidential, and stating the source of the information as well as contact details of the Submitting Parties.

i. All Users will refrain from any attempt to identify individuals when using the anonymized data. If a User finds or suspects that anonymized data in combination with protected or publicly available data may lead to the identification of individuals (triangulation), either through normal data processing or through newly developed tools, this will immediately be reported to the Curator.

j. On a report mentioned in the former paragraph, the Curator group will assess the possibility of triangulation, its cause and probability, and report through the Curator to the European Data Protection Board or the appropriate national supervisory authority.

k. Collaborating Participants based outside Europe (i.e. outside EU/EEA) hereby accept and undersign compliance to European laws and rulings on data protection. If access to person-identifying data is granted, a participant based

outside the EU/EEA must undersign an additional data protection agreement, unless an EC adequacy decision for its country already exists. This agreement will be attached to this document.

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l. The terms of this agreement shall survive the HEVnet repository system by 5 years from the close of the system.

m. Changes and amendments to this Agreement must be made in writing in order to be valid. This shall also apply to any amendment of this requirement for written form. Any rights established under this Agreement may only be waived in writing.

n. Should any provision of this Agreement be or become invalid, ineffective or unenforceable, the remaining provisions shall remain valid. The Parties undertake to replace the invalid, ineffective or unenforceable provision by a valid, effective and enforceable provision which comes as close as possible to the economic interests of the Parties. This shall also apply in the event of a contractual gap.

o. In case of any dispute arising in connection with this Agreement the Parties will attempt to find an amicable solution. All disputes arising from or in connection with this Agreement and are not under the mandatory legal responsibility of the hosting organization, shall be decided by the Curator Group.

This Agreement shall be governed by Dutch Law.

Access to the protected working space will be controlled through login names and passwords. Login names and passwords will be issued by the administrator only after completing and signing this Agreement.

Explanatory Memorandum

I. Scope of the document

This agreement does not describe the structure, governance and standard operation procedure of the Network. This is done elsewhere. The confidentiality and due diligence agreement is stating the ownership of, and responsibilities for the sharing of data in the data repository system HEVnet. It is additionally meant to be a code of conduct clarifying the do's and don'ts for the parties participating in HEVnet. Its aim is protecting the integrity of the database and the Network as a whole, and promoting constructive peer collaboration. Effort has been made to draw up the agreement in a way that it is legally unambiguous, but also readable and understandable for participants who are not legally qualified.

II. Assumptions

The agreement is drawn up in a way that leaves flexibility for the conference of participants to decide, also in a later stage, on issues as who can participate and the nature of data to be shared.

- The possibility of participation of public and private partners is taken into account, from different domains and within as well as outside the EU. If partners from outside the EU are admitted, they declare to comply with EU legislation
- The sharing of anonymized data is understood as the default, but the agreement takes into account the possibility of sharing person-identifying data. In the latter case Partners from outside EU/EEA need to sign an additional agreement.

III. Open data

One of the broader developments is the increasing demand for open sharing of publicly acquired data. See Directive EU/2013/37 (making the re-usability of public sector information compulsory since 2015) and strong policies on open data both on national and EU level (e.g. the EC requirements on Horizon2020 research projects). To comply to open data policies and as a preemptive response to requests of third parties to the publication of data, the confidentiality agreement takes into account 2 phases. Each participant need to check if the sharing of data in this way is allowed under their national law:

- First the all data are uploaded to a protected working space of HEVnet to which only have access eligible participants who have undersigned this agreement,
- After a certain period of time, which is for the pilot set at 18 months, the data fall into the public domain, but not before being scrutinized and stripped of all privacy and other sensitive elements (meta-data).

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If otherwise is decided the Agreement must be adjusted.

IV. Protection of special data

If HEVnet actually will use the possibility of (temporarily) sharing person-identifying data in the protected environment, this can be legally based on the exemption of article 9(i) (“public interest in the area of public health”) of the EU General Data Protection Regulation (EU/GDPR), but only if additional domestic law of the submitting party(s) exists, affirming this exemption. The confidentiality agreement suffices for secrecy, but additionally a separate document has to be drafted in compliance with articles 26 to 29 of the EU/GDPR, to define the ‘joint controllers’ and capture the controller and processor responsibilities. This is mandatory law but can in principle be executed as a one time job. If desired, the sharing of subsets of data can of course also be limited to smaller groups for different studies.

V. Jurisdiction

As now is understood, HEVnet will function as an EU collaborative instrument, but the actual data repository, software tools and functional support will be placed in The Netherlands.

After expert consultation the agreement is proposed under Dutch law, given the fact that the database is under the responsibility of a Dutch hosting organization and the conclusion that data are well protected under Dutch, and where applicable European, public law.

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17.06.2019

The RIVM-HEVnet team

hevnet@rivm.nl

Herewith, I(name)

Datum
17 June 2019

working at(name institution)

as.....(function)

in(location institution)

declare that I accept the conditions for participation in HEVnet as outlined in the 2019 Confidentiality and Due Diligence Agreement for participation in HEVnet and will abide by them.

Signed:.....

Date:(day)/(month)/20.....

Location:.....

Email:.....@.....

Telephone: +.....

Please scan signed form and send it by mail to: hevnet@rivm.nl.