Data Access Agreement of the study
Integrative genomic profiling of large-cell neuroendocrine carcinomas reveals distinct subtypes of high-grade neuroendocrine lung tumors (EGAS00001000708)

This agreement governs the terms of access to the controlled access datasets generated by the Department of Translational Genomics of the University of Cologne, Medical Faculty. In signing this agreement, you agree to be bound by the terms and conditions of access set out therein.

For the sake of clarity, the terms of access set out in this agreement apply to the User and to the User Institution(s) (as defined below). The current agreement is limited to the data set EGAS00001000708 (as defined below) and does not cover other data generated at the different centres participating in the project.

Definitions

Data Producer:	Department of Translational Genomics of the University of Cologne including the collaborators of the study "Integrative genomic profiling of large-cell neuroendocrine carcinomas reveals distinct subtypes of high-grade neuroendocrine lung tumors"
External Collaborator:	A collaborator of the User, working for an institution other than the User Institution(s) (see below for definitions of User and User Institution(s)).
Data set:	The Controlled Access Datasets of the study EGAS00001000708 generated by the Data Producer.
Project:	Integrative genomic profiling of large-cell neuroendocrine carcinomas reveals distinct subtypes of high-grade neuroendocrine lung tumors
Research Participant:	An individual having contributed their personal data to the project.

User: An applicant (principal investigator), having signed this Data Access Agreement, whose User Institution has co-signed this Data Access Agreement, both of them having received acknowledgement of its acceptance.

User Institution(s): Institution(s) at which the User is employed, affiliated or enrolled. An authorized representative of it has co-signed this Data Access Agreement with the User and received acknowledgement of its acceptance.

Terms and Conditions:

In signing this Agreement:

1. The User and the User Institution(s) agree to use the Data solely for the advancement of medical research. Use of the data for the creation of products for sale or for any commercial purpose including research with third parties for commercial purposes is not permitted.

2. The User and the User Institution(s) agree to use the Data for no other purpose than the approved purpose and project described in the collaboration proposal; use of the Data for a other/new purpose or project will require a new application and approval.

3. The User and the User Institution(s) agree to preserve, at all times, the confidentiality of the information and Data set. In particular, they undertake not to use, or attempt to use the Data set to compromise or otherwise infringe the confidentiality of information on Research Participants.

4. The User and the User Institution(s) agree to protect the confidentiality of Research Participants in any research papers or publications that they prepare by taking all reasonable care to limit the possibility of identification.

   The User and the User Institution(s) agree not to pursue any research with the goal to identify Research Participants and not to link or combine the Data set provided under this agreement to other information or archived data available in a way that could re-identify the Research Participants, even if access to that

data has been formally granted to the User and the User Institution(s), or is freely available without restriction.

5. The User and the User Institution(s) agree not to transfer or disclose the Data set, in whole or part, or any material derived from the Data set, to anyone not listed in this application form, except as necessary for data safety monitoring, national audits or program management. Should the User or the User Institution(s) wish to share the Data set with an External Collaborator, the External Collaborator must complete a separate Collaborator's Form for Access to the Data set.

6. The User and the User Institution accept that the Data are protected by and subject to national and international laws, including but not limited to the General Data Protection Regulation (GDPR) and that the User and the User Institution are responsible for ensuring compliance with any such applicable law. User Institutions located outside the EU/EEA (European Economic Area) are requested to additionally enter into the **Standard Contractual clauses for the transfer of personal data to Third countries** in their updated form. (Set of Standard Contractual Clauses according to *Commission Implementing Decision (EU) 2021/914 of 4 June 2021 (Module 1, Controller to Controller)* attached).
The Consortium Data Access Committee reserves the right to request and inspect data security and management documentation to ensure the adequacy of data protection measures in countries that have no adequate national laws on data protection comparable and up to the standard which is established and mandatory in the EU.

7. The User and the User Institution(s) accept that Data producers, depositors or copyright holders, or the funders of the Data set or any part of the Data set supplied:
     a) bear no legal responsibility for the accuracy or comprehensiveness of the Data set;
     b) accept no liability for indirect, consequential, or incidental, damages or losses arising from use of the Data set, or from the unavailability of, interruption in Data set access for whatever reason and;
     c) bear no responsibility for the further analysis or interpretation of these Data set, over and above that published by the Consortium.

8. The User and the User Institution(s) agree not to make intellectual property claims on the Data set (including somatic mutations) and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of the Data set, or conclusion drawn directly from the Data set.

9. The User and the User Institution(s) can elect to perform further research that would add intellectual and resource capital to the data set and decide to obtain intellectual property rights on these downstream discoveries. In this case, the User and the User Institution(s) agree to implement licensing policies that will not obstruct further research and to follow –if applicable- the U.S. National Institutes of Health Best Practices for the Licensing of Genomic Inventions, or a similar national guideline that is in conformity with the OECD Guidelines for the Licensing of the Genetic Inventions: OECD (2006), *OECD Guidelines for the Licensing of Genetic Inventions*, OECD Publishing, Paris, https://doi.org/10.1787/9789264018273-en-fr..

10. The User shall be free to publish the results of the research using the Data for the approved purpose. The User agrees to acknowledge in any such publication that the research makes use of Data generated by the Data Producer.

11. The User and the User Institution(s) agree to destroy any Data held, once it is no longer used for the indicated project described in this application form unless obligated to retain the data set for archival purposes in conformity with national audits or legal requirements.

12. The User and the User Institution(s) will notify the Data Access Committee as soon as they become aware of a breach of the terms or conditions of this agreement.

13. The User and the User Institution(s) agree that they will submit a final report to the Data Access Committee sixty (60) days on completion of the agreed purpose. The Data Access Committee agrees to treat the report and all information, data, results, and conclusions contained within such report as confidential information belonging to the User Institution.

14. If requested, the User and the User Institution(s) will allow data security and management documentation and corresponding physical installations to be inspected to verify that they are complying with the terms of this Data Access Agreement.

15. This Agreement shall be effective as of the date of the last party to sign below ("Effective Date") and shall terminate three (3) years after the Effective Date, unless terminated sooner pursuant to Section 16 below.

16. The User and the User Institution(s) accept that this agreement may terminate immediately upon any breach of this agreement from the User and the User Institution(s). Either Party may terminate this Agreement upon thirty (30) days written notice for any reason.

17. In case of section 15 or 16 the User and the User Institution(s) will be required to destroy any Data held, including copies and backup copies. This clause does not prevent the User and the User Institution(s) from retaining the data set for archival purpose in conformity with national audits or legal requirements.

18. The following Sections of this Agreement shall survive its expiration or termination: Sections 1-11, 13-15, 19.

19. The User and the User Institution(s) agree to distribute a copy of this agreement, explain its content to any person mentioned in this application form and obtain their approval on observing the regulations as laid out.

20. This agreement shall be construed, interpreted and governed by the laws of Germany and shall be subject to the non-exclusive jurisdiction of the German courts.

For and on behalf of User:
Name of Applicant(s): _____
_____
_____
_____

Signature of Applicant(s): _____
_____
_____
_____

Date: _____

For and on behalf of User Institution:

**Signature of
Institutional or
Administrative
Authority:** _____

Print name: _____

User Institution: _____

Date: _____

For University of Cologne, Department of Translational Genomics

_____
Signature

ROMAN THOMAS
_____
Print Name

_____
Date

**For Universitätsklinikum Köln AöR, Abteilung Drittmittel
Institutional Representative**

_____
Signature

Petra Schreiner-Kaub
_____
Print Name

_____
Date

Attachment:

Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council

-Module I Transfer Controller to Controller-