Agreement

on the Use of Data and/or Biomaterial from the Study [Study name]

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between

University Medicine Greifswald
Public corporation
Fleischmannstrasse 8
17475 Greifswald

represented by the Board of Directors

Executing institution:
Forschungsverbund Community Medicine
at University Medicine Greifswald

(in the following "**UMG**")

and

«Institution»

Institution

«Street no.», «Post code» «City»

Address

represented by:
(Name, function of the person authorised to represent the institution)

(in the following "**User**")

Project Manager: **"Applicant"**

(in the following "**Project Manager**")

the following **Agreement** is concluded:

§ 1 Definitions

For the terms used in this Agreement, the standardised definitions apply in accordance with § 1 of the UMG's Terms of Use for Data and Biomaterials (in the following referred to as the Terms of Use, Annex) of the studies supervised by the FVCM, in particular SHIP, SNiP, and GANI_MED.

§ 2 Subject of this Agreement

(1) The subject of this Agreement is the use, obligations and rights in connection with the Data and Biomaterials provided in accordance with § 1 (3) of the Terms of Use:

☐ Initial Application for Use

☐ Supplementary Application

for Data and/or Biomaterial use from "Study_Type"

from	"Application date"
with the reference number	"Business reference"
under the project title	"Title"

The Terms of Use and the Application for Use as well as the formal approval form an integral part of this Agreement. This includes, in particular, the legal basis for use stated in the Terms of Use.

(2) The Data Use in accordance with subsection 1 is granted to the User exclusively within the scope of and in accordance with the Application for Use approved by the FVCM.

(3) If only Data and no Biomaterials have been handed over, all clauses on Biomaterials in this Agreement are void.

§ 3 Right of Use for Data and Biomaterials

(1) The User is granted a limited, non-exclusive and non-transferable right to use the Data and Biomaterials provided in accordance with § 2(1) for the duration of and in accordance with the Usage Agreement.

§ 4 Responsibilities of User, Project Manager and Project Participants

(1) The User must ensure and guarantee that the Project Manager or Project Participants working for the User comply with the provisions of this Agreement when using the Data and/or Biomaterials provided from «Studie_Typ» and that they fulfil the obligations incumbent on them when executing this Agreement.

(2) The Project Manager is the FVCM’s primary contact for all questions relating to the Project Using the Data or Biomaterials. The Project Manager must ensure that the FVCM’s requirements for the Project Using the Data or Biomaterials are coordinated with all Project Participants and Users.

(3) If the Project Manager leaves the institution, the User must immediately nominate a successor to the FVCM Board of Directors.

(4) The User must ensure that the departing Project Manager and other departing Project Participants no longer have access to the Data and/or the Biomaterial or the data obtained from the Biomaterial after that person departs from the User. In particular, the User is responsible for creating the data protection conditions required by this Agreement. If Project Managers and other Project Participants who leave the project under this provision are to retain their access, this must be reported to the Data and Biomaterial Transfer Office in writing without delay. UMG reserves the right to object with a notice period of 4 weeks.

(5) If the Project Manager continues to carry out the Project Using the Data or Biomaterials at a new institution, a new agreement must be concluded with the new institution and the existing agreement with the User must be terminated in writing if necessary.

(6) The publication rights arising for the respective Project Participant in relation to UMG from the following provisions with regard to the Results Data obtained before the Project Participant's departure remain unaffected.

§ 5 Duration of Project and Use; Deletion, Return and Destruction Periods

(1) The Project Using the Data or Biomaterials begins on «Zeitraum_von» and ends on «Zeitraum_bis» (project duration).

(2) Any remaining Biomaterial must be returned by <<date>>, deviations are regulated by subsection 5.

(3) The physical deletion of the Project Data and the destruction of the Biomaterials must take place on «Zeitraum_bis_1», deviations are regulated by subsection 5.

(4) At these times, the User or the Project Manager sends the following information to the FVCM:

- written notification of the deletion of the Data,
- written notification of the return of remaining Biomaterial or that the Biomaterial has been used up.

(5) An Opt-Out Application approved by the FVCM for renewing the period of use of the Data/Biomaterials automatically supplements and extends the term of this Agreement as per subsection 1 until the completion date specified in the application without any further adjustment to this Agreement. Accordingly, the date of deletion of the Data/Biomaterials specified in subsections 2 and 3 are then extended until 5 years thereafter.

§ 6 Requirements, Agreements and Conditions

[Additional requirements, agreements and conditions]

§ 7 Use of the Data and/or Biomaterial

(1) UMG assures that it has received all necessary positive votes from the relevant ethics committee(s) and duly signed required consent forms from the relevant sample and Data donors or their representatives for the provision of the sample Biomaterial and Data to the User and that the consent forms cover the intended (research) purpose of this Agreement.

(2) The User and the Project Manager are obligated to use the Data and Biomaterials provided to them exclusively for the requested and approved use and only within the period for which the application was made. Only the parameters that have been applied for and approved by the FVCM Board of Directors may be measured or determined. The requirements and conditions contained in the official approval must be complied with. Any further use of the Project Data and Biomaterials must be applied for separately.

(3) The right of use is not transferable.

(4) It is not permitted to copy or forward—in either pseudonymised or anonymised form—Data and/or Biomaterial to third parties. The exception described in subsection 5 applies.

(5) If objectively justified, anonymised Project Data may be made publicly accessible (e.g., in journals) with the written permission of the FVCM. In this case, the User must submit a separate, informal written application to the FVCM describing all Data elements that are to be made publicly accessible. It must be clear from the application why the Data concerned can be regarded as anonymised. In cases of doubt, UMG's data protection officer can be consulted.

(6) The User must carry out its work within the scope of this Agreement to the best of its knowledge and belief, taking into account the state of the art in science and technology.

(7) Pooling of Project Data with any other data is not permitted without prior written authorisation from the FVCM as part of an approval.

§ 8 Data Protection

(1) The Parties undertake to observe and comply with data protection regulations (in particular Regulation (EU) 2016/679 (GDPR)) as amended from time to time. They regard themselves as joint controllers as described in Art. 26 GDPR and have set out their rights and obligations under Art. 26 GDPR in Annex 1 to this Agreement.

(2) The Parties must take all necessary technical and organisational measures to ensure an appropriate level of data protection in accordance with Art. 24, 32 GDPR and to guarantee the rights of the data subjects, in particular in accordance with Chapter 3 GDPR, within the statutory time limits at all times.

(3) UMG is responsible for transmitting the Data to the User. Users who receive Data and/or Biomaterial within the scope of this Agreement are themselves responsible for compliance with the relevant legal provisions, in particular the data protection laws in the respective applicable version, as of the point in time when they receive the Data and/or Biomaterial.

(4) All Contracting Parties must inform each other immediately and in full if errors or irregularities in data processing or violations of the provisions of this Agreement or applicable data protection law (in particular the GDPR) are detected.

(5) Each Party is obliged to inform the other Party immediately if a data protection supervisory authority contacts them and this relates to processing covered by this Agreement.

(6) The Parties will coordinate their response to enquiries from supervisory authorities regarding the contractual processing, insofar as this is legally permissible and/or reasonable.

(7) The Parties agree that regulatory measures must always be complied with. Nevertheless, the Parties will consult with each other as to whether and to what extent appeals will be lodged against the authority's orders.

(8) The provisions on data protection will remain valid until the processing of personal data on the basis of the contract has ended, irrespective of the periods specified in § 5.

§ 9 Publication Rights, Property Rights, Subsequent Use of Data and Biomaterials, Archiving

(1) The transferred Data and Biomaterials remain the property of UMG at all times. All personal Results Data and Biomaterials based on the Data and Biomaterials become the property of UMG.

(2) The User is not permitted to sell the transferred Data and/or Biomaterials.

(3) Techniques, scripts for generating Results Data or for processing Biomaterials introduced by the User remain the property of the User.

(4) Personal Results Data must be made available to the FVCM in full and in a suitable electronic form, including documentation (e.g. analysis scripts), after completion of the analysis and preparation of the Data prior to their use in Publications, but at the latest within one year of completion of the requested period of use (§ 5(1)). UMG receives a non-exclusive, free, irrevocable, worldwide right to use the personal Results Data for storage, dissemination and further processing for non-commercial purposes.

(5) Without the express written consent of UMG, the User and the Project Participants are not permitted to apply for any patents or other industrial property rights relating to Data from «Studie_Typ» or to Data obtained from «Studie_Typ» Biomaterial or which are based on such Data.

(6) In the case of joint inventions, UMG and the User will conclude a separate agreement on the use, patenting and commercialisation of this joint invention.

(7) Any commercial use of the Results Data (e.g. for diagnostic screening or therapeutic intervention) by UMG or the User requires a separate contractual agreement between both parties.

(8) In the event of further utilisation of the Results Data, the User must be offered a share by the FVCM for a period of 10 years after the end of the project. This is deemed to have been fulfilled if the contact details of the Project Manager stored at the FVCM are used for this purpose. The User does not have the right to veto further use.

(9) UMG archives the submitted analysis syntaxes for a maximum period of 10 years after the end of the project, including the specific analysis datasets on which the Publications are based. Instead of a physical copy of the Data, it is sufficient for UMG to save the rules with which the Data was selected and processed, provided that the Data used can be restored.

§ 10 Publication of Project Data

(1) The rights to the use and publication of the Project Data for the requested purpose will remain exclusively with the User or the Project Manager until two years after the end of the project (§ 5(1)). During this period, any use by the FVCM or third parties may only take place with the consent of the User.

(2) If written Publications are based in whole or in part on Data and/or Biomaterial from «Studie_Typ» or Project Data, an acknowledgement must be made of the Project Using

the Data or Biomaterials from which the Data originate, as specified in Annex 2. Adjustments can be made in consultation with the Publication Steering Committee of the FVCM. Enquiries should be addressed to: pc@med.uni-greifswald.de.

(3) Manuscripts must be submitted to the Publication Steering Committee for a formal review at least 14 days before submission to a journal or publisher. The tasks of the Publication Steering Committee are described in the Terms of Use.

(4) The User must inform the Data and Biomaterial Transfer Office (transferstelle@med.uni-greifswald.de) in writing by «Zeitraum_bis_1» (= 1 year after the end of the Project Using the Data or Materials) at the latest about all Publications that have been produced on the basis of the Data and/or Biomaterial provided. If Publications appear after the end of the Agreement, the reporting obligation also extends to these. This includes the citation with an existing Document Object Identifier (DOI), if applicable, as well as author copies in electronic form.

§ 11 Confidentiality

(1) The Parties must treat all documents marked CONFIDENTIAL as well as all documents which, in terms of their content and/or nature, must be understood as confidential by a competent person, as confidential for a period of at least 5 years and must not make them accessible to third parties.

(2) This does not apply to documents and information that (a) were already known to the User, (b) were already publicly known or become publicly known through no fault of the User, (c) have demonstrably been developed independently by the User, (d) are made accessible to the User by a third party authorised to do so or (e) must be made accessible to a third party due to an official order or court order.

§ 12 Liability

(1) The User is aware that Data and Biomaterials may contain inherent errors and risks. Biomaterials can be infectious, for example. The User is responsible for taking necessary precautions for the appropriate handling of Data and Biomaterials. UMG is not liable for damage of any kind caused by contact with and work on the Biomaterial provided.

(2) UMG assumes no guarantee or other liability for the completeness and correctness of the content of the transmitted Data or the suitability of the Data and any Biomaterials for the purpose of use assumed by the User and permitted under the Usage Agreement.

(3) The Parties are liable to affected persons in accordance with the statutory provisions.

(4) In the internal relationship, each Party is liable to the other Party in accordance with Art. 82 GDPR for the damage caused by processing in its area of responsibility. This also applies with regard to fines, insofar as legally permissible, if these were imposed due to a circumstance that was the responsibility of another Party.

§ 13 Legal Consequences of Violations of Restrictions and Conditions of Use

(1) If restrictions on use and conditions of use arising from this Agreement are breached with regard to the Project Data/Biomaterial, UMG may withdraw the User’s authorisation to use

the Data in whole or in part with immediate effect by written declaration of the FVCM Board of Directors.

(2) This applies in particular under the following conditions, although this list is not exhaustive:

- the property rights of UMG are disregarded
- the use exceeds the authorised scope
- the obligation to return, destroy or delete is not fulfilled
- the Results Data are not made available to the FVCM despite a request to make them available
- the publication rights are disregarded.

(3) If the authorisation of use is revoked, the use of the Data and/or Biomaterials provided must be discontinued immediately, the Project Data must be deleted immediately and any unused Biomaterials must be returned immediately.

(4) Further claims of UMG, in particular in the event of culpable violations, remain unaffected.

§ 14 Transfer of Data and Biomaterials

(1) If Biomaterial is issued to the User for further analyses, the access regulations under §§ 2 and 3 of the Terms of Use apply. The pseudonymised Biomaterial is transferred by:

Institut für Klinische Chemie und Laboratoriumsmedizin Diagnostikzentrum, Ferdinand-Sauerbruch-Straße, D - 17487 Greifswald Email: transfer-ikcl@med.uni-greifswald.de Tel.: (03834) 86-5500

The Biomaterial will be handed over in accordance with the procedure described in § 8 of the Terms of Use

on:

to: *(not applicable if only Data is transferred)*

(2) The transfer of **Data (for SHIP)** is carried out by:

Institut für Community Medicine Abteilung SHIP/KEF Email: transferstelle@med.uni-greifswald.de Tel.: 3834 86-7541

The transfer of Data will be carried out

on:

to: «Titel» «Vorname» «Name»

(3) The User is responsible for providing the necessary co-operation to enable the transfer of the contractual encrypted Data. Please direct any questions in connection with the transfer of Data and Biomaterials as well as the return transfer to: transferstelle@med.uni-greifswald.de

§ 15 Costs

(1) No fees are charged for the transfer of Data and Biomaterials.

(2) No costs will be charged to UMG by the User for transferring the Results Data, documents and Biomaterials to UMG.

§ 16 Duration of Agreement

(1) The Agreement enters into force upon signature by both Contracting Parties. The Agreement ends with the complete fulfilment of the stated deletion, return and destruction deadlines, reporting obligations and any additional requirements, agreements or conditions stated in this Agreement.

(2) The contractual obligations arising from the clauses mentioned above will continue to apply after termination of the Agreement.

§ 17 Final Provisions

(1) There are no verbal ancilliary agreements. Amendments or additions to this Agreement must be made in writing with the signatures of both Parties. The written form with signatures requirement also applies to the waiver of this written form requirement.

(2) Should any provision of this Agreement be or become invalid or unenforceable, this will not affect the validity or enforceability of the remaining provisions. The Contracting Parties will endeavour to replace the invalid or unenforceable provision with a valid or enforceable provision that comes as close as possible to what was originally intended, taking into account the interests of both Parties. The same applies to filling an unintended loophole.

(3) The Agreement is subject to German law including the GDPR.

(4) The place of fulfilment and legal venue is Greifswald. With the consent of UMG, it is possible to agree on a different legal venue in Germany.

(5) If there is a contradiction with the Terms of Use, this Agreement applies.

Annexes:

☒ Annex 1 Agreement according to Art. 26 GDPR
☒ Annex 2 Information on acknowledgements
☐ FVCM Terms of Use
☐ FVCM Approval

Other annexes:

☐ FVCM Application for Use
☐ Application for an associated project

University Medicine Greifswald

.....

Greifswald, Date

_____

Head of the Data and

Biomaterial Transfer Office

User:

.....

Location, Date

_____

(Person authorised to represent the institution)

Acknowledged with approval:

Project Manager:

Location, Date

_____

Annex 1 Agreement according to Art. 26 GDPR

University Medicine Greifswald and the User regard themselves as joint controllers as described in Art. 4(7) of the General Data Protection Regulation (GDPR).

The definition of the purposes and means of data processing, as well as the type of personal data, is described in the Application for Use, which is attached to this Agreement. (Application for Use)

The division of tasks between the University Medicine Greifswald and the User with regard to the catalogue of obligations of the GDPR is as follows:

Catalogue of obligations DSGVO	**University Medicine Greifswald**	**User**	**Document / Participants on the UMG side**
Art. 26(1): Determine the purposes and means of processing	**X**	**X**	Application for use of data and material
Art. 26(1): Determine the type of personal data	**X**	**X**	Application for use of data and material
Art. 26(2): Informing the parties concerned about the essential contents of this Agreement	**X**		Participation information
Art. 13: Information to be provided where personal data are collected from the data subject	**X**		Participation information and declaration of consent
Art. 14: Information to be provided where personal data have not been obtained from the data subject	**X**		Participation information and declaration of consent
Art. 15: Processing information access requests	**X**	**X**[1]	SHIP Subject management
Art. 16: Processing information rectification requests	**X**		SHIP Subject management
Art. 17, 18, 19: Processing requests for erasure, restriction of processing, notification of the obligation to erase	**X**	**X**[1]	SHIP Subject management
Art. 20: Processing requests for transmission (data portability)	**X**	**X**[1]	SHIP Subject management SHIP Subject management
Art. 21: Processing objections	**X**		SHIP Subject management
Art. 24, 32, 35, 36: Definition/documentation of TOMs, risk assessment	**X**	**X**	Data protection concept of the SHIP study
Art. 28: Involvement of processors or sub-processors and their review	**X**		For the User only with the authorisation of the FVCM
Art. 30: Maintaining records of processing activities	**X**	**X**	SHIP Subject management
Art. 33, 34: Reporting data breaches	**X**	**X**	SHIP Subject management

1 In order to support the University Medicine Greifswald in processing such enquiries.

Annex 2 Information on acknowledgements

In Publications, adequate reference must be made to the requested Data source. The following text passages are provided for orientation purposes.

In consultation with the Publication Steering Committee, these texts can be further adapted to specific requirements. If you have any questions, please contact the Publication Steering Committee (pc@med.uni-greifswald.de). Updates to the requirements for acknowledgements are possible.

SHIP-START

Acknowledgements

SHIP is part of the Community Medicine Research net of the University of Greifswald, Germany, which is funded by the Federal Ministry of Education and Research (grants no. 01ZZ9603, 01ZZ0103, and 01ZZ0403), the Ministry of Cultural Affairs as well as the Social Ministry of the Federal State of Mecklenburg-West Pomerania, and the network 'Greifswald Approach to Individualized Medicine (GANI_MED)' funded by the Federal Ministry of Education and Research (grant 03IS2061A).

Addition for Genotype data (Affymetrix array)

Generation of ExomeChip data was supported by the Federal Ministry of Education and Research (grant no. 03Z1CN22).

Addition for Genotype data (ExchomeChip array)

Generation of ExomeChip data was supported by the Federal Ministry of Education and Research (grant no. 03Z1CN22).

Addition for MRI data (Affymetrix array)

Whole-body MR imaging was supported by a joint grant from Siemens Healthineers, Erlangen, Germany and the Federal State of Mecklenburg West Pomerania.

SHIP-TREND

Acknowledgements

SHIP is part of the Community Medicine Research net of the University of Greifswald, Germany, which is funded by the Federal Ministry of Education and Research (grants no. 01ZZ9603, 01ZZ0103, and 01ZZ0403), the Ministry of Cultural Affairs as well as the Social Ministry of the Federal State of Mecklenburg-West Pomerania, and the network 'Greifswald Approach to Individualized Medicine (GANI_MED)' funded by the Federal Ministry of Education and Research (grant 03IS2061A).

Addition for Genotype data (Illumina Omni 2.5 array)

The SHIP authors are grateful to Holger Prokisch and Thomas Meitinger (Helmholtz Zentrum München) for the genotyping of the SHIP-Trend cohort.

Addition for Genotype data (ExchomeChip array)

Generation of ExomeChip data was supported by the Federal Ministry of Education and Research (grant no. 03Z1CN22).

Addition for MRI data (Affymetrix array)

Whole-body MR imaging was supported by a joint grant from Siemens Healthineers, Erlangen, Germany and the Federal State of Mecklenburg West Pomerania.

Addition for DNA-Methylation data

DNA methylation data have been supported by the DZHK (grant 81X3400104).

Additional notes for SHIP cohorts

Addition for the Methods if blood biomarkers (incl. for DNA, RNA, etc.) were used

Serum aliquots were prepared for immediate analysis and for storage at -80 °C in the Integrated Research Biobank (Liconic, Liechtenstein).

Cohort reference publication (should be cited):

Völzke, H. *et al.* PMID: 35348705

Data sharing statement

The data of the SHIP study cannot be made publicly available due to the informed consent of the study participants, but it can be accessed through a data application form available at https://fvcm.med.uni-greifswald.de/ for researchers who meet the criteria for access to confidential data.

Ethics statement

The study was allowed under the recommendations of the Declaration of Helsinki. The medical ethics committee of the University of Greifswald approved the study protocol, and oral and written informed consents were obtained from each of the study participants.

GANI_MED

Acknowledgements

GANI_MED was initially funded by the Federal Ministry of Education and Research (grant 03IS2061A) and by the Ministry of Education and Research of the State of Mecklenburg-West Pomerania.

SNIP

Acknowledgements

SNiP is part of the Community Medicine Research Network of the University Medicine Greifswald, which is supported by the German Federal State of Mecklenburg- West Pomerania.