Contract
concerning the use of data and/or samples from the study ,,Leben und Gesundheit in Vorpommern‘‘/ Study of Health in Pomerania (SHIP)

The following **contract** is hereby concluded

between the **Universitätsmedizin Greifswald** (University Medicine Greifswald)
corporation under public law
represented by the board of management
Fleischmannstraße 8
DE-17475 Greifswald
Germany

executive branch: Forschungsverbund Community Medicine (Community Medicine Research Alliance) der Universitätsmedizin Greifswald

(hereinafter referred to as “**University Medicine Greifswald**“ or “**FVCM**“)

and

_____
Institution

_____
Address

Represented by: _____
(Name and position of the designated responsible person)

Accountable scientist:

(hereinafter referred to as “**Institution“** or “**Project**“)

I Definitions

(1) “***Data***“ are, for the purpose of this contract, the adjusted raw data stemming from various examinations, where appropriate after their release by the Data Safety and Monitoring Committee of the FVCM.

Non-adjusted data and non-released data are on no account to be made available. The same applies for data allowing a personal identification (names, addresses, etc.).

(2) “***Use of data***“ means, for the purpose of this arrangement, the perusal or statistical evaluation of all data or a part thereof for scientific publications or lectures, for the recruitment of representative samples for follow-up studies, or the preparation of further statistical evaluation activities.

(3) The classification “***samples***“ or “***sample material***“ means, for the purpose of this contract, all biological materials which have been gained from research subjects in SHIP. Among these materials are, for example (but not exclusively) blood, serum, plasma, microbiological mouth and pharyngeal swabs, urine, saliva and materials which are gained from these materials such as blood products and DNA.

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Detailed information as to the sample material stored in the sample inventories can be found in the SHIP laboratory handbooks and project descriptions.

(4) "***Accountable scientist***" means, for the purpose of this agreement, the main applicant for the use of data and/or material which form the basis of the project. A project can have more than one accountable scientist. In such cases, all accountable scientists are jointly and severally subject to all rights and duties.

(5) "***Project data***" are, for the purpose of this contract, all results gained by the project from the SHIP data supplied or the assigned SHIP sample material.

II Subject Matter of the Contract

(1) The subject matter of this contract is the assignment and use of data and/or sample material from the SHIP study as described in the application of the project for the use of data material and/or sample material from SHIP

of	[date]
with the reference number	[reference number]
under the project title	[titel]

The application is included in this agreement as Appendix 1.

(2) The data and/or the sample materials are assigned to the project exclusively for use and exploitation in the context and constraints of the application submitted by the project, within the requested time frame and under observation of any and all covenants or restrictions stipulated by the board of directors of FVCM at the time of their approval of the application as well as all precise provisions of this contract.

(3) Data and sample material remain at all times the property of the University Medicine Greifswald.

(4) The Institution which receives data and/or sample material in the context of this contract accepts full liability for the compliance with all pertinent legal requirements, especially but not exclusively the data protection laws in their respective versions.

(5) In addition, the institution is obliged to comply with the principles of "Good scientific practice"[1] and "Good epidemiological practice"[2] in the use and exploitation of the assigned data and/or samples.

III Appointment of the Accountable Scientist

(1) The Institution is responsible for ensuring that the appointed scientist shall comply with the conditions of this agreement and fulfil all obligations incumbent on him or her in the context of carrying out this contract pertaining to the use and exploitation of data and/or samples from SHIP.

(2) In the event that the appointed scientist leaves the institution, the institution must appoint a successor without delay and inform the board of the FVCM.

[1] Recommendations of the committee „Selbstkontrolle in der Wissenschaft" – Vorschläge zur Sicherung guter wissenschaftlicher Praxis, Deutsche Forschungsgemeinschaft, Januar 1998 („self-regulation in science" – proposals for safeguarding good scientific practices, published by the German Research Alliance, January 1998)
http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/download/empfehlung_wiss_praxis_0198.pdf.

[2] Leitlinien und Empfehlungen zur Sicherung von Guter Epidemiologischer Praxis (GEP) der Deutschen Gesellschaft für Epidemiologie (DGEpi) (Guidelines and recommendations for safeguarding good epidemiological practices (GEP) of the German Society of Epidemiology (DGEpi)
The current German version can be viewed at www.dgepi.de.

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(3) The institution is responsible for ensuring that the departing accountable scientist has no further access to the data, the sample material, or any data gained from the sample material once he has left the institution. This applies similarly for all other employees who leave the institute.

(4) Having left the existing institution, should the departing scientist wish to retain control of the project in his new position, then the contract with the existing company must be annulled and a new agreement concluded with the future facility.

(5) In the matter of project data collated prior to his leaving the project, those publication rights relating to the respective employee and the University Medicine Greifswald which are detailed in the here following conditions remain unaffected.

IV Duration of Project

(1) The project begins on
and concludes on

(2) The return of any remainder material
must take place by at the latest

(3) The physical deletion of the data
must take place by at the latest.

(4) At these points in time, the accountable scientist shall communicate the following information to the FVCM:
- written notification as to the deletion of the data,
- written notification as to the return of the remainder material.

V Use and Exploitation of the Data and/or Sample Material

(1) The institution and the accountable scientist are obliged to use and exploit the entrusted data exclusively for those purposes applied for and approved, and solely within the duration specified in the application. The conditions and covenants contained in the approval must be observed. Any and every additional use of the data and/or samples must be applied for anew. The right of use and exploitation is not transferable.

(2) In the event that sample material is analysed by the project, both the institution and the accountable scientist are duty-bound to use the material exclusively for the purposes applied for and solely within the laboratories of the institution. Only the parameters applied for and approved by the board of the FVCM may be determined. Any and every additional use of the data and/or samples must be newly applied for from the board of the FVCM.

(3) The copying and dissemination of data and/or sample material to third parties is prohibited. Should it be required to set this prohibition aside, a separate approval must be applied for from the board of the FVCM.

VI Conditions and Covenants

[specific definitions]

VII Obligation to Report

(1) The accountable scientist is to report to the board of FVCM on the progress of activities and the status of the project. This report is to be made on a yearly basis until the conclusion of the project

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(2) The accountable scientist is to provide the board of the FVCM with a concluding report of the project in written and electronic form. This report is to be handed over by, at the latest, [date] (= one year after the conclusion of the project).

VIII Surrender and Administration of Project Data

(1) The accountable scientist must provide the FVCM with the complete project data after the analysis and preparation of the data, in any event at the latest within one year of concluding the project. (Part IV, Section 1) The data have to be supplied in a suitable electronic form.

(2) An intrinsic part of this condition is the provision of an adequate, self-explanatory documentation of the project data. The required format for the electronically supplied data are to be arranged in conjunction with the data manager of the results data base at the transfer centre of the FVCM. The data must be readable on a readily available, everyday form of software. It is especially important that the data be stored and accessible in the smallest practical data unit size.

(3) Using such project data, the FVCM is forming a central database within the transfer centre. Applications to the FVCM for access to this database and the use of these data can be made by other scientists as of two years after the conclusion of the project in which the respective data were created. The institution will be informed of the communication of the project data generated by its project. The scientist or the facility which receives the data will be reminded that the principles of good scientific practice are applicable with regard to participation of the institution or the accountable scientist whose project generated the initial results.

IX Ownership Rights/Commercial Exploitation

(1) Without express written permission from the University Medicine Greifswald, no patents or other protection rights which are based in whole or part on SHIP data or on data deriving from SHIP material or on the project data may be registered by the institution or accountable scientist.

(2) Any and every commercial exploitation of the data and/or material and the project data are prohibited, including but not exclusively: screen broadcasts or presentations, intervention with survey subjects, manufacturing or sale.

X Publication Rights

(1) Until the expiry of two years after the conclusion of the project (as defined in Part IV, Section 1), the institute or the accountable scientist and his project staff dispose exclusively over the rights for the utilisation and publication of the project data. During this period, use of the data on the part of the FVCM or third parties may only take place with the permission of the accountable scientist.

(2) After the expiry of the two years' limit, the University Medicine Greifswald will receive an independent right of exploitation of the project data for the FVCM. The continued rights of publication on the part of the institution and/or the accountable scientist and his project staff remain unaffected by this.

(3) The FVCM is aiming for a use of the new variables generated by the data made available to the project - for example new categories or scores and indices, as well as information gained from the sample material – in cooperation with the accountable scientist and/or his project staff. The principals of "Good Scientific practice"[3] and

[3] Recommendations of the committee „Selbstkontrolle in der Wissenschaft" – Vorschläge zur Sicherung guter wissenschaftlicher Praxis, Deutsche Forschungsgemeinschaft, Januar 1998 („self-regulation in science" – proposals for safeguarding good scientific practices, published by the German Research Alliance, January 1998

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"Good epidemiological practice"[4] apply to all planned and future exploitation and use of the project data.

(4) The University Medicine Greifswald can freely dispose over the project data after the expiry of the two years' limit and may, via the FVCM, provide other cooperation partners with these data without prejudice to the provision contained in Section 3. The accountable scientist should be consulted in the event of an exploitation of the project data on the part of the FVCM and be appropriately considered in the case of publication.

(5) The following rules of publication, as listed in Part XI of this document, apply to all published works in which data or sample material from SHIP or project data from earlier projects are used.

(6) In the course of the coordination between himself and the FVCM as provided for under Part X of this document, the accountable scientist is obliged to observe the rights of his project staff and to incorporate these rights, where appropriate, in the respective decisions. If no agreement can be reached in this respect, then the board of the FVCM is to be informed of this without delay.

XI Rules for the Publication of Project Data

(1) For the purposes of these rules, "***Publications***" or "***Printed Matters***" are understood to include manuscripts, monographs, abstracts, congress and conference articles, videos, CD-ROMs, graphic images, audiotapes and similar works which are created by the institution or its participating staff and in which data originating from SHIP or from sample material originating from SHIP are used and/or exploited.

(2) In the case of written publications based on data and/or sample material from SHIP or project data, an acknowledgement must be inserted to the effect that data and/or sample material have been provided by the Study of Health in Pomerania (SHIP) from the Community Medicine Research Alliance of the Medical Faculty at the Ernst Moritz Arndt University of Greifswald. The patron (BMBF – Federal Ministry for Education and Research) and subsidy identification codes (01ZZ9603, 01ZZ0103, 01ZZ0701) are to be given.

(3) Before a manuscript is handed over for any form of publication to a scientific magazine or a publisher, it is to be presented for inspection of the Publication Steering Committee (PSC) of the FVCM, which advises on and coordinates publishing activities based on the SHIP data and/or the SHIP sample material. In this respect the PSC is charged in particular with the following duties:

- Assurance of the adherence to the rules of publication. In the event of transgressions, the PSC is to seek an amicable solution. In serious cases the PSC shall inform the board of the FVCM and, should it be necessary, subsequently the general meeting of members of the FVCM, which shall take the final decision on the conflict situation.

- Decisions as to the methodical compatibility of the planned publication with the design and aims of SHIP. Manuscripts, which have been created with the assistance of data and/or samples from SHIP and which in the considered opinion of the PSC for methodical reasons contradict the design or objectives of SHIP, may not be published.

http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/download/empfehlung_wiss_praxis_0198.pdf.

[4] Leitlinien und Empfehlungen zur Sicherung von Guter Epidemiologischer Praxis (GEP) der Deutschen Gesellschaft für Epidemiologie (DGEpi) (Guidelines and recommendations for safeguarding good epidemiological practices (GEP) of the German Society of Epidemiology (DGEpi)
The current German version can be viewed at www.dgepi.de

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- Inspection of the concurrence in content between the submitted manuscripts and other, previously published or as yet unpublished, results from the FVCM. The PSC is to bring possible conflicts with other results to the attention of the authors with the minimum possible delay. The aim of this measure is to ensure a coherent and conflict-free presentation of the results from SHIP.
- The PSC is to make its decision within a maximum of two weeks and to inform the applicant in writing of the result.

(4) Inasmuch as they may extend beyond the aforementioned regulations, the "Empfehlungen der Deutschen Forschungsgemeinschaft zur Guten Wissenschaftlichen Praxis (gemäß Verlautbarung vom 15.12.1997)" (Recommendations of the German Research Alliance for Good Scientific Practice, as per the official announcement of 15.12.1997) and the "Leitlinien für Gute Epidemiologische Praxis der Deutschen Gesellschaft für Epidemiologie (DGEpi, aktuelle Version unter www.dgepi.de" (Guidelines for Good Epidemiologic Practice of the German Society of Epidemiology, DGEpi, the current German version can be viewed at www.dgepi.de) are to be followed.

(5) After the appearance of the publication, the accountable scientist is to provide the FVCM with a specimen copy.

XII Deletion of the Data and Return of Unused Sample Material

(1) The accountable scientist is obliged to delete all data from SHIP which were supplied to the project by the FVCM as well as the project data at the latest five years after the end of the project. The board of the FVCM is to be informed in writing of the deletion.

(2) Any and all sample material which was provided for analysis for the required purposes and which remains unused or incompletely used must be made available for return to the FVCM directly after the analysis. This must be carried out in such a way that guarantees the further exploitation and use of the leftover sample material. The board of the FVCM is to be informed in writing about the return of the leftover materials

(3) The obligation of safekeeping of the original data from SHIP used in publications is to be undertaken by the transfer centre of the FVCM. The University Medicine Greifswald is to ensure that the original data are available to be viewed or post-analysed by the project at a later time. (cf. "Empfehlung 6.1 der Leitlinien für Gute Epidemiologische Praxis der DGEpi "[5] - Recommendation 6.1 of the Guidelines for Good Epidemiological Practice).

XIII Confidentiality

(1) The institution and the accountable scientist are obliged to handle all documents, which were received from the FCVM or the University Medicine Greifswald and are labelled VERTRAULICH (confidential), with the utmost confidentiality for a period of at least five years and in this time to afford third parties no access to these documents.

(2) This does not apply to documents and information which (a) were already known to the recipient, (b) were already known to the general public or become publicly known by no fault of the recipient, (c) have been provably developed independently by the recipient himself, or (d) were made accessible for the recipient by a third party who was entitled to do so.

[5] Leitlinien und Empfehlungen zur Sicherung von Guter Epidemiologischer Praxis (GEP) der Deutschen Gesellschaft für Epidemiologie (DGEpi) (Guidelines and recommendations for safeguarding good epidemiological practices (GEP) of the Deutschen Gesellschaft für Epidemiologie (DGEpi)
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XIV Liability of the University Medicine Greifswald

(1) Data and sample material can contain inherent errors and damaged elements. Sample material can be infectious.

(2) The University Medicine Greifswald accepts no responsibility for the correctness of the transferred data or the suitability of such data and sample material for a particular purpose. This liability exclusion does not apply in the event of a deliberate act.

(3) The University Medicine Greifswald accepts no liability for damage of any kind which is caused by contact with or work on the sample material provided. This does not apply in the event that the University Medicine Greifswald fails to inform the institution or the accountable scientist of a contamination in the sample material which was known to the University Medicine Greifswald prior to its providing the sample material.

(4) Furthermore, the University Medicine Greifswald can only be held liable under the terms of this contract in the event of deliberate acts or gross negligence. With the exception of deliberate violations of its obligations, the University Medicine Greifswald is not liable for collateral damage.

(5) The aforementioned limitations of liability also apply to the legal liability of the University Medicine Greifswald and the personal liability of its representatives, employees and vicarious agents.

XV Liability of the Institution

(1) The liability of the institution to the University Medicine Greifswald for damages, especially such damages as may be caused by unauthorised or incorrect usage and/or dissemination of data, sample material or project data, are regulated according to prevailing law.

(2) Furthermore, the institution is to indemnify the University Medicine Greifswald against any and all claims from third parties for damages and injunctive relief, which arise out of an inappropriate behaviour on the part of project.

XVI Legal Consequences in the Event of Transgressions against Conditions of Use and Restrictions on Use

(1) In the event of transgressions against the conditions of use and restrictions on use contained in this contract in respect of the data, sample material and project data, the University Medicine Greifswald can rescind the permission for use previously issued to the institution with immediate effect by way of written declaration by the board of FVCM.

(2) This applies in particular but not exclusively in the event that:

- the proprietary rights of the University Medicine Greifswald (Part II, Section 3) are violated
- the usage exceeds the permitted extent as defined in Part V
- a breach of the duty of confidentiality in violation of Part XIII takes place
- the duty to report as per Part VII is not fulfilled despite request
- the project data are not made available to the FVCM despite request in accordance with Part VIII
- the regulations detailed in Part XI are violated.

(3) In the event that the permission for use is withdrawn, the usage of the data and/or samples is to be discontinued without delay, both the data and the project data are to be deleted without delay and any unused sample material is to be returned without delay.

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(4) All further rights of the University Medicine Greifswald, namely in the event of culpable infringements, remain unaffected.

XVII Delivery of the Data and Samples

(1) The handover of the sample material is carried out by:

Institut für Klinische Chemie und Laboratoriumsmedizin
Director: Univ.-Prof. Dr. med. Matthias Nauck
Diagnostikzentum
Ferdinand-Sauerbruch-Straße, 17475 Greifswald, Germany
Email: matthias.nauck@uni-greifswald.de
Telephone: +49 03834 86-5500

The handover of the sample material is to take place on:

Given to: inapplicable

(2) The handover of the data are carried out by:

Institut für Community Medicine
Abteilung Versorgungsepidemiologie und Community Health
Ellernholzstr. 1/2, 17487 Greifswald, Germany
Email: mohamad.habes@uni-greifswald.de
Telephone: +49 03834 86-7523

The handover of the data are to take place on:

Given to:

XVIII Costs

Data
A protective charge of €100 is to be paid for the delivery of the data. This sum is due upon receipt of the data and must be transferred by the project to the following bank account within 14 days: Account number 230005454 at the Sparkasse Vorpommern (Sort Code 150 50 500) with the advice notice: “DRM-IES03 GZ [case number]“.

Sample Material
A protective charge of €250 + €1 per sample and type of material is to be paid for the delivery of the sample material.
The total sum arising from this calculation is due upon receipt of the sample material and must be transferred by the project to the following bank account within 14 days: Account number 230005454 at the Sparkasse Vorpommern (Sort Code 150 50 500) with the advice notice: “DRM-IES03 GZ [case number]“.

XIX Duration of Contract

(1) The contract becomes valid upon being signed by both contract parties. The contract expires upon the complete fulfilment of all obligations for delivery and reporting arising from the provisions of Parts VII, VIII and XII.

(2) The obligations arising from the provisions of Parts IX, X, XI, and XIII remain in force even after the expiry of the contract.

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XX Final Provisions

(1) Verbal subsidiary agreements are not valid. Amendments or extensions to this contract must be made in writing. This also applies to any waiver of the provision for amendments to be made in writing.

(2) Should any provision or other part of this contract be deemed or become invalid, the remaining provisions shall be inviolate and remain in force. The parties to the contract shall replace the invalid provision with a valid and enforceable clause which is similar in content and meaning to the originally intended provision whilst observing the interests of both parties. The same solution shall be applied to the settling of unintended gaps in the contractual provisions.

(3) This contract is subject to German law. Place of fulfilment and jurisdiction is Greifswald.

University Medicine Greifswald
Greifswald,

Prof. Dr. W. Hoffmann, MPH
Vice Chairman, FVCM Managing Board

Institution
(Place and date)

(Authorised representative)

Acknowledged and approved:

Accountable scientist:
(Place and date)

Sample