University Medicine Greifswald

Terms

of Use for Data and Biomaterials

from the Studies Supervised by the FVCM

from 20 April 2024

Preamble

The Research Network Community Medicine (FVCM) of the University Medical Centre Greifswald (UMG) aims to provide research partners with regulated access to subject data and biomaterials. This applies in particular to the studies:

- Study of Health in Pomerania (SHIP-START, SHIP-TREND, SHIP-NEXT)
- Survey of Neonates in Pomerania (SNiP)
- Greifswald Approach to Individualised Medicine (GANI_MED)

These Terms of Use regulate the process of applying for and accessing subject data and biomaterials.

The Terms of Use, together with the Application for Use and the Usage Agreement (user not affiliated with the UMG or the University of Greifswald (UG)), or the declaration of consent (Project Managers within the UMG, UG), form the basis for using the requested data and materials.

§ 1 Definitions

(1) **Data** within the meaning of these Terms of Use are pseudonymised data about personal and factual circumstances as well as any examination or laboratory results of study participants and subjects. The Data were collected with the subjects' consent for the purposes defined in the respective studies. The Data available for use by third parties can be found in the data manuals, laboratory manuals and project descriptions of the studies.

(2) **Biomaterials** are all biological materials collected from test subjects. This includes, for example: blood; placental tissue; microbiological mouth, tongue and throat swabs; urine; saliva; stool samples; hair samples; and other materials obtained from these, such as blood components and DNA. The types of Biomaterials stored in the sample banks can be found in detail in the data manuals, laboratory manuals and project descriptions of the studies.

(3) The **Application for Use** contains a description of the specific purpose of use, the desired duration, methods and Project Participants as well as the specific statement of the required Data and Biomaterials. Data and Biomaterials must be selected in accordance with the principle of data minimisation.

There are three forms of Applications for Use:

(4) An **Initial Application** is the first Application for Use submitted for a Project Using the Data or Biomaterials. It forms the necessary basis for the transfer of Data and Biomaterials by the FVCM.

(5) A **Supplementary Application** is an Application for Use that includes a later amendment of the Application for Use on which it is based. Supplements can thus be requested as follows:

a) by researchers who realise after concluding the Usage Agreement that this supplementary Data must be included in the approved use,

b) when third parties need to use the Data beyond the scope of the Usage Agreement, in particular for external analyses (Data Transfer Supplement).

A Supplementary Application cannot be used to significantly change the purpose of use. This would require a new Application for Use.

The Supplementary Application only becomes effective once a new Usage Agreement has been signed. This Usage Agreement extends the term as requested.

(6) An **Opt-Out Application** is an Application for Use that includes a later, small amendment of the Application for Use on which it is based with a simplified approval procedure. Supplements can thus be approved as follows:

a) the subsequent request of Data to a small extent of up to 20 variables without changing the purpose of use.

b) an extension of up to an additional 3 years for the agreed period of use, in particular the project duration (time supplement).

The Opt-Out Application does not require a new Usage Agreement to be signed.

(7) **Data Use** means the use of the requested Data and/or Biomaterials to pursue the purposes specified and approved in the application, e.g. for statistical analyses, scientific publications or teaching purposes.

(8) The **Project Using the Data or Biomaterials** refers to the research project for which the application for the use of Data or Biomaterial was submitted by the Project Manager in the form in which it was approved and became the subject of the Usage Agreement.

(9) A **User (Contractual Partner)** is a legal entity that carries out the project and becomes a Contractual Partner of the FVCM through the legally effective conclusion of the Usage Agreement (e.g. a university corporation as the legally responsible body of a legally dependent institute or another dependent research institution). The User is the legal representative of the Project Manager. If several institutions have access to Data in a project, each of these institutions is a User as defined by these Terms of Use.

(10) **Project Participants** are all persons named on the Application for Use in addition to the Project Manager and their employees. All Project Participants must be registered on the FVCM application page.

(11) The person who creates and submits the application is the **Project Manager** as defined by these Terms of Use.

(12) **Principal Investigators** in these Terms of Use are the scientists responsible for carrying out a study administered by the FVCM with regard to applying for and accessing subject data and biomaterials.

(13) **Results Data** are the evaluation results obtained in the project from the Data provided for use and, if applicable, Biomaterials (including any measurement data on Biomaterials). In addition, data derived from the Data provided and Biomaterials, if applicable, are part of the Results Data.

(14) The term **Project Data** describes the totality of the Data and the Results Data or Biomaterials provided.

(15) **Publications** are manuscripts, monographs, abstracts, congress and conference papers, videos, CD-ROMs, graphics, audio tapes or similar for which Project Data has been used within the scope of these Terms of Use.

§ 2 Purpose of these Terms of Use

(1) These Terms of Use describe the basis for access to Data and Biomaterials for the studies supervised by the FVCM.

(2) In addition to these Terms of Use, the following regulations as amended must be observed by the User and the FVCM:

a) data protection regulations (at state, federal and EU level)

b) votes of the responsible ethics committees

§ 3 Subject of these Terms of Use

(1) These Terms of Use apply to all Data elements and Biomaterials of the studies managed by the FVCM.

(2) UMG's FVCM is responsible for managing Data and Biomaterials and deciding on their use in accordance with these Terms of Use.

§ 4 Legal Basis for Using Data and Biomaterials

(1) The Data and Biomaterials collected are based on the voluntarily given informed consent of the subjects in accordance with the respective subject information and consent form. The prerequisite for transferring Data and Biomaterial is the consent of the subjects to the extent required for the project in question.

(2) Any use of Data and Biomaterial requires a written Application for Use. The FVCM must decide on the requested Data Use (Approval of Use) on the basis of the steps set out in § 6. A Usage Agreement must be concluded for each Data Use if the Data or Biomaterials are transferred to a User outside UMG, and a declaration of consent to these Terms of Use must be signed if the Data or Biomaterials are transferred within UMG or UG.

(3) The User is obliged to use the Data and Biomaterials provided exclusively for the requested and approved use and only within the period for which the application was made. The specifications, requirements and conditions contained in the declaration of consent or in the Usage Agreement must be complied with.

(4) If Biomaterials are provided, the User may only use the Biomaterials for the purposes requested and only in the laboratory named in advance. Only the parameters that have been applied for and approved by the FVCM may be measured or determined. Any further use of the Biomaterials must be applied for separately with the FVCM.

(5) The transfer and use of Data or Biomaterials requires the UMG/UG Project Manager to sign a declaration of consent or the User to sign a legally binding Usage Agreement. The director of the Data and Biomaterial Transfer Office must also sign the declaration of consent or the Usage Agreement.

§ 5 Data Protection, Property Rights, Derivation of Funding

(1) Property rights and data protection are regulated in the Usage Agreement.

(2) Commercial use is regulated in the Usage Agreement.

(3) The User cannot derive any entitlement to financial or other funding or support from University Medicine Greifswald from the approved Data Use.

§ 6 Applying for Data and Biomaterials

Applying for Data or Biomaterials by means of Applications for Use, Supplementary Applications and Opt-Out Applications is regulated as follows:

(1) The Project Manager applies for the Data from the FVCM via the FVCM Data and Biomaterial Transfer Office. The online form "Application for the transfer and use of data/biomaterials" is used for this purpose. Required information in the application includes: the specific purpose of use, the desired duration, methods, Project Participants, recipients of the Data/Biomaterial, selection of the Data and Biomaterials needed for this.

(2) The application for MRI imaging data is submitted as an “application for an associated project for data generation”.

(3) Both the Project Using the Data or Biomaterials and the MRI associated project must specify in the application exactly which parameters are to be redetermined.

(4) The start and end of the Project Using the Data or Biomaterials must be stated in the application. It should be noted that the initial project duration is limited to a maximum of 3 years. An extension of the project duration is possible using a Supplementary Application.

(5) Free-text entries on required Data and Biomaterials are only permitted if the necessary information is not available in the selection screen.

§ 7 FCVM’s Review of the Applications

(1) Upon receipt of the Application for Use, the Data and Biomaterial Transfer Office ensures the Application is forwarded to the FVCM Board of Directors.

(2) The FVCM Board of Directors decides on the Applications after taking note of them and discussing them internally, taking all votes into account. The FVCM Board of Directors examines the Applications with regard to compliance with the rules, coverage by declarations of consent, scientific feasibility, data minimisation, potential conflicts with other projects and whether the interests of third parties are affected. The Ethics Committee is consulted if there is any uncertainty about ethical issues related to the Data Use.

(3) As a rule, the FVCM Board of Directors meets monthly to discuss Applications for Use that are submitted properly.

(4) In order to be processed, Applications for Use must generally be submitted one week before the next meeting date.

(5) Additional procedures when applying for Biomaterials.

When applying for Biomaterials,

a) one or two reviewers must be appointed by the spokesperson of the FVCM Board of Directors to review the quality of the Application content, and
b) the director of the IKCL must be consulted to check the requested sample type and quantity.

In contrast to this, when applying for Biomaterials from GANI_MED,

a) one or two reviewers must be appointed by the GANI_MED Network Coordinator (or a representative nominated by the Coordinator) to review the quality of the Application content, and
b) the director of the IKCL must be consulted to check the requested sample type and quantity.

(6) The FVCM decides on Applications for contacting test subjects with the consent of the respective study managers; these Applications require a specific justification.

(7) The Board of Directors takes one of the following decisions:

a) Approve Application
b) Approve Application with Revisions
c) Reject Application

(8) The decision of the Board of Directors may be subject to conditions and requirements.

(9) For urgent Applications for the use of Data and Biomaterials, the Application can be approved by a “spokesperson’s decision” upon justified request by the Project Manager.

a) With the approval of at least two spokespersons if the Data and/or samples are to remain at the UG or UMG and there is no objection.
b) With the consent of all three spokespersons if Data and/or samples are to be sent to an institution other than the UG or UMG.
c) The decision on this procedure will be a report item at the next regular meeting of the Board of Directors.

(10) Further provisions for Supplementary Applications and Opt-Out Applications:

a) These may only be submitted if the Initial Application has been approved.
b) They are typically submitted by Project Managers of the Initial Application upon which these Supplementary and/or Opt-Out Applications are based. In exceptional cases, they may also be submitted by Project Participants from the Initial Application. The justification for one of these Applications for Use being submitted by the Project Participants must be included in the respective Application for Use. In this case, responsibility for the project is transferred to the applicant.
c) These types of applications can be submitted several times. It is up to the FVCM to decide whether the requirements for an Opt-Out or Supplementary Application are still fulfilled for subsequent applications.

(11) Opt-Out Applications can be processed using the ***opt-out*** **procedure**. In this procedure, an application labelled as an Opt-Out Application is circulated to the FVCM Board of Directors. If no objection is received within two working days, the Opt-Out Application is deemed to have been approved. In the event of an objection, the Opt-Out Application will be the subject of a decision at the following FVCM Board of Directors meeting.

(12) The result of the decision is sent to the Project Manager in writing by the Data and Biomaterial Transfer Office.

a) Following a positive decision by the FVCM Board of Directors, the contracts and declarations of consent are drawn up by the Data and Biomaterial Transfer Office.

b) Once the contracts and declarations of consent have been signed and returned, the Data and any Biomaterials are handed over.

(13) The Principal Investigator for the studies to be administered by the FVCM may, in consensus with the FVCM Board of Directors, decide on a right of veto for the Principal Investigator for the study in the approval process for Applications for Use as a prerequisite for the processing of studies by the FVCM. This procedure serves to protect the interests of individual studies vis-à-vis the FVCM. The decision must be recorded in writing.

§ 8 Release of Data and Biomaterials

(1) The technical procedure and process for releasing the authorised Data or Biomaterials is regulated separately by the Principal Investigators for the respective studies. The Principal Investigators for the respective studies are responsible for data protection and IT requirements.

(2) The Principal Investigators for the respective studies are responsible for ensuring that Data and Biomaterials are only handed over in accordance with the scope requested.

§ 9 Release of Manuscripts for Publication

(1) Manuscripts must be submitted to the Publication Steering Committee at least 14 days before submission to a journal or publisher. The Publication Steering Committee is limited to the following tasks:

(1) Ensuring compliance with the publication rules. The Publication Steering Committee will seek an amicable solution for any violations. In serious cases, the Publication Steering Committee will inform the FVCM Board of Directors, which will make the final decision on the conflict.

(2) Checking that the content of the submitted manuscripts corresponds to the requested purpose of use.

(3) Ensuring compliance with patent protection, no violation of confidentiality interests, no conflict with data protection regulations.

(4) Reviewing the Acknowledgements (for requirements, see Appendix 2)

(5) The Publication Steering Committee usually decides on a submitted manuscript within 5 working days of receipt. The Project Manager will be informed of the result in writing. If no feedback is given by the Publication Steering Committee within 4 weeks, the manuscript is considered approved for publication in the submitted form.

§ 10 Personal, Identifying Data

(1) Personal, identifying data (name, address) are not made accessible to the User.

(2) If it is necessary to contact the test subjects, this will be done by the test subject management team responsible for the respective study. Establishing contact in connection with Data Use requires a positive vote by the FVCM Board of Directors and the persons responsible for the respective study and, if necessary, a positive vote by the Ethics Committee.

(3) The User and all Project Managers or Project Participants must not make any attempt to re-identify persons.

§ 11 Entry into Force and Transitional Provisions

(1) In accordance with § 35 of the University Charter (Grundordnung) of the UG, these Terms of Use enter into force on the day following their public announcement.

(2) These Terms of Use replace the former terms of use "Regulations of the University Medicine Greifswald on the use of Data and sample Biomaterial of the studies "Life and Health in Western Pomerania" (SHIP) "Community Medicine in the Newborn Age" (SNiP) "Greifswald Approach to Individualised Medicine" (GANI_MED)" from 03 July 2012 for all Data and Biomaterial usage agreements concluded starting 01 February 2024. The former terms of use remain in force for ongoing Projects Using the Data or Biomaterials. Supplementary Applications for ongoing Projects Using the Data or Biomaterials can only be contractually regulated on the basis of these Terms of Use.

Issued on the basis of the resolution of the Faculty Council of UMG from ... and the UG Senate hearing on ....

Greifswald, [Date].....

Scientific Board of Directors
at University Medicine Greifswald
Universitätsprofessor Dr. Karlhans Endlich