The Steering Committee of the Core Unit Systems Medicine (CU-SysMed) enacted during its meeting on May 6th, 2013, the following regulations and guidelines for the operation and use of the Core Unit Systems Medicine at the Medical Faculty.

§ 1 Type of Operation
The Core Unit Systems Medicine (CU-SysMed) is a facility of the Medical Faculty at the University of Wuerzburg. Its leader is directly subordinated to the Executive Board ('Fakultätsvorstand') of the Medical Faculty.

§ 2 Mission
1. The CU-SysMed is responsible to manage, operate and make available the instruments of the CU-SysMed to support research, teaching and training.

2. In particular, the CU-SysMed provides in the frame of its capacities the following services:
   a. Support grant applications;
   b. Consulting and support of planning, preparing and implementing of research projects;
   c. Provision of technologies and expertise;
   d. Where appropriate, execution of experiments by the personnel of the CU-SysMed;
   e. Bioinformatical analysis;
   f. Optimisation and adaption of existing technologies and methods to the specific needs of custumers;
   g. Contribution to training and education;
   h. Evaluation of improvements or further developments of technologies and methods, as well as testing new instruments.
§ 3 Leadership

1. The leader of the Core Unit Systems Medicine is appointed by the Executive Board ('Fakultätsvorstand') of the Medical Faculty and is responsible for:
   a. implementing the structure of the CU-SysMed and its services in the frame of available capacities and in agreement with the Steering Committee;
   b. the overall operations and the appropriate execution of the tasks;
   c. cost calculations and invoicing;
   d. proof of the appropriate utilisation of resources given to the CU-SysMed;
   e. efforts for acquisition of third parties' grants;
   f. adaption of the CU-SysMed to changing requirements;
   g. the matter of utilisation of the CU-SysMed such as
      i. deciding on the admission of users and customers, if needed in consultation with the Steering Committee,
      ii. coordinating projects,
      iii. setting priorities,
      iv. counselling interested users of the CU-SysMed.

2. In line with the tasks of the CU-SysMed, the leader or any of his deputies and the leaders of the sub-units have managerial authority to personnel and users while executing the experiments in the facilities of the CU-SysMed.

§ 4 Users

1. Users and customers of the CU-SysMed can be the institutes of the Medical Faculty, the research groups and chairs of the university hospitals, interdisciplinary research centers and structured research networks, or chairs and research groups of other faculties at the University of Wuerzburg who want to approach the offers of the CU-SysMed to fulfill their obligations in research and teaching, or for their studies.

2. Other individuals or organisations may be based on contractual agreements allowed access as far as the rights of users defined by §4 (1.) are not reasonably limited.

3. §4 (2.) is effective also for individuals defined in §4 (1.) if they use the services for ancillary activities.

4. Regulations about the implementation of research funded by third parties are not affected.
5. The Policies and Regulations of Operation of the Core Unit Systems Medicine have to be made part of the registration form and other contracts or agreements, also with third party funds.

§ 5 Admission and Registration

1. To guarantee smooth handling of all inquiries, the priority will be defined by the leader of the CU-SysMed.

2. The admission will be granted depending on available resources. For the sequence of handling, the time of submission will be considered. Cases of exception or priority conflict that seems to be not resolvable can be referred to the Steering Committee.

3. To assess demand and volume, a counselling free-of-charge has to be offered before use or service. The CU-SysMed recommends to be contacted as early as possible, at best already during the planning phase. An early established contact allows optimal mutual consent of the proposed project from experimental design till bioinformatical data analysis. It avoids mistakes in calculating time and costs already during the planning or (grant) application phase.

4. For project-specific support (‘Projektbezogene Unterstützung’) a registration form is required that displays a project title and provides a 200-300 words abstract. Further, it describes the desired services, and defines the initiator/contact person and the sponsor. The form has to be signed by the initiator and sponsor.

5. During the implementation of the project, direct contact of User and executing personnel of the CU-SysMed has to be guaranteed.

6. The leader of the CU-SysMed may ask for an application in writing. In particular, the purpose and the putative volume have to be explained, and the initiator named.

§ 6 Steering Committee

1. The work of the leader of the CU-SysMed is supported and reviewed by the Steering Committee.

2. The leader reports regularly on the activities of the CU-SysMed to the Steering Committee.
3. The Steering Committee consists of 10 members. Beside the Dean of the Medical Faculty, members are speakers of structured research networks and research centers (e.g. IZKF, RVZ, CCC MF, or SFBs) as well as two representatives of the Faculties of Biology and Chemistry. The list of members is published on the internet page of the CU-SysMed.

   a. The meetings of the Steering Committee are arranged by the leader of the CU-SysMed. All members are invited at least 2 weeks in advance. The leader of the CU-SysMed will join the meetings as a guest with advisory vote only.

   b. It is a task of the Steering Committee, to set priorities in agreement with the leader of the CU-SysMed if capacities are limited or help to resolve conflicts.

   c. The Steering Committee debates and decides on expanding the areas of technologies or necessary instrumentation to address new research activities or to support requests from the users defined in §4.

   d. The Steering Committee comes to a decision at simple majority of the members present. At least 5 members with voting rights have to be present to constitute a quorum. At balance of votes, the Dean’s vote counts twice.

§ 7 Obligations of the Users
The Users are obliged,

1. to respect the rules of the Regulations. In particular, refrain from all that could negatively influence the operations of the CU-SysMed;

2. in the offices and labs of the CU-SysMed as well as when using their instruments and space to follow absolutely the advise by the personnel of the CU-SysMed;

3. to indicate any risk to the personnel of the CU-SysMed that might be adherent to the experimental material (in particular about pathogen, infectious, toxic, radioactive or any other harmful properties);

4. if requested to confirm that research projects and experiments have been noticed and approved (especially the approval of the generation and/or use of genetically modified organisms, experiments with animals and if legally requested approval by ethic commissions). Material derived from patients has to be handled according to the data protection act by the user and provided to the CU-SysMed in anonymised form without any exception;
5. if necessary to provide personnel with specific licenses to perform the experiments. The use of instruments and performance of experiments is only allowed by personnel certified by the CU-SysMed;

6. to reference the work of the CU-SysMed in publications according to good practice in science:
   a. In general, all third party contribution to a scientific project, as it has been generated for example by the work performed by the CU-SysMed, has to be clearly referenced, e.g. in the materials and methods section. The pure payment of a fee or charge for a service does not replace a correlating reference of the technical or scientific work.
   b. Depending on volume and complexity of the work or based on a collaboration agreement, the CU-SysMed or individuals of its members should be recognised in the acknowledgement\(^1\) or by co-authorship. A co-authorship of a CU-SysMed scientist requires typically a significant intellectual input beyond the pure performance of experiments or analysis.
   c. The CU-SysMed should be informed before the submission for publication. Preferentially, the correlating data should be handed in for review beforehand. For reference, a copy of the article should be made available to the leader of the CU-SysMed upon publication.

The User / project leader is recommended to make the data publically available in appropriate data bases (e.g. those of the NCBI, such as GEO, Trace or SRA) along with the publication of the correlating scientific results.

§ 8 Liability

1. The liability of the CU-SysMed to Users defined in §4 Abs. 2 and 3 is limited to deliberate intention or gross negligence, if legal regulations allow at all. The CU-SysMed does not take any defects liability for samples or consumables material.

\(^1\) Please consider the following wording example for your acknowledgement section: „This work was supported by the name of the sub-unit, part of the Core Unit Systems Biology (CU-SysMed) at the Medical Faculty, University of Wuerzburg, Germany.”
2. Users according to the definition in § 4 Abs. 1 and Abs. 2 and Abs. 3 shall be liable to the requirements defined by statutory provisions. This accounts particularly for harm, that is caused due to nonobservance of the User's duties, lack of elucidation about risks or failure to follow the procedures or instructions by the CU-SysMed staff.

3. It is the User's responsibility to ensure, that external storage devices for data transfer are not contaminated by any viruses or other malware. For harm, which is resulting from such infected external data storage device, the User shall be the User's liability.

4. The reliability for the quality of materials and/or data that are handed over to the CU-SysMed is with the User.

§ 9 Exclusion and Restrictions of the Right of Use

1. Authorisation may be excluded, revoked or retroactively restricted particularly if
   a. no adequate registration form is handed-in,
   b. the information provided in the registration form is not correct or not correct anymore,
   c. a defined and agreed user fee is not paid,
   d. the Policies and Regulations of Operation or directions by the leader of the CU-SysMed are breached or future violations may be suspected,
   e. the CU-SysMed is not properly referenced according to §7 Abs. 6 in publications.

2. The User cannot claim for damage resulting from such exclusion, revocation or retroactive restriction.

§ 10 Refund

1. Proposed by the CU-SysMed and in accordance with the Department of Finance at the University, the Steering Committee determined a defined and graded catalog of fees (attachment). The fees are graded according to internal and external academic users, each either for purely taking services or for collaborations, which are honored with price reductions. To external commercial users special rates apply. The calculations of the rates for internal users should consider a contribution to the costs for personnel, service contracts, - based on the expected degree of capacity utilisation -, and reserves for repairs and purchases of spare parts, as well as the full compensation of consumables.
2. Users of the category defined in § 4 Abs. 1 may benefit from reduced rates to encourage application of certain technologies and to generate base for further grant applications.

3. For use of the CU-SysMed in accordance with § 4 Abs. 2, true costs including overheads have to be applied. Special rates including overheads apply to industrial users to keep market prices in balance.

4. Projects to further develop technologies or methods including feasibility studies that are of interest to the Core Unit Systems Medicine may in agreement with the Steering Committee and under a collaboration agreement benefit from significantly reduced rates or might, exceptionally, run even without costs. In turn co-authorship of members of the CU-SysMed on resulting publications accordingly to their scientific or technical contributions is expected.

5. Fees apply only to project-specific support, not to initial counselling. Before the start of services against payment, a cost estimation (quote) will be submitted to the User. If there is agreement between User and service unit about each party’s contribution, a registration form will be signed. Should the estimated costs reach 120% of the initial offer, the User / sponsor has to be informed immediately for approval before more work is invested that be brought to account. In case that the 120% line is exceeded without permission of the User/sponsor, the additional costs beyond the 120% line have to be taken by the CU-SysMed.

6. Accounting of the service fees will be done after completion of the services by invoice. If larger amounts apply, consumables or a subtotal may be invoiced separately after purchase and receipt by the CU-SysMed. Should the submitted cost center not have sufficient coverage, then the superior hierarchy cost center (e.g. of the institute, department or clinic) will be charged. The amount invoiced is due within one month after date of invoice.

§ 11 Data Storage and Data Transfer
The principles of protection of data privacy and correlating legal requirements, in particular according to the Bundesdatenschutzgesetzes (BDSG), have to be observed while working with personal data, also as outlined in §7 Abs. 4.

1. All submitted data, for example such from external sequencing, and such derived from own experiments will be stored on a server for further processing. High volumes of data e.g. from high-throughput sequencing projects may be stored on serves of external contractors. Consequently, additional costs might incur, which will be invoiced to the correlating User.
2. For the first, data storage is free of charge. For larger volumes of data, the project leader may be approached to contribute external storage capacity.

3. Primary sequencing data (e.g. in FastQ format) will be stored maximally for 1 year after completion of the project. Afterwards, the project leaders are responsible and pay for data storage. In view of the interests also of the other Users, the CU-SysMed aims to free space as soon as possible for running projects. Therefore, the project leaders should as soon as their primary data are analysed look for own storage capacity to allow submission of their data latest 3-6 months after completion.

§ 12 Commencement
These Policies and Regulations of Operation are coming into effect in agreement with the Steering Committee of the CU-SysMed and with the executive board (‘Fakultätsvorstand’) of the Medical Faculty the day after announcement to the faculty.

Würzburg, den 27.5.2014

Prof. Dr. Matthias Frosch Dr. Eberhard Krauß
(Dekan der Medizinischen Fakultät) (Leiter der Core Unit Systemmedizin)

References:
DFG-Anforderungen an Nutzungsordnungen von Gerätezentren.
Betriebs- und Entgeltordnung der Core Facility Genomics der Medizinischen Fakultät der Universität Ulm.
Nutzerordnung für die Zentrale Serviceeinheit Medizinische Biometrie und Statistische Bioinformatik, Georg-August-Universität Göttingen.