

Rules of procedure for the BMBH

§ 1 Status

1. The BioMaterialBank Heidelberg (BMBH) is an organizational association of quality assured biobanks in Heidelberg with a central administration, common operating procedures and platform structures (data and quality management as well as technology platforms). The BMBH is under the auspices of the Medical Faculty Heidelberg, the German Cancer Research Center (DKFZ) and the Heidelberg University Hospital (UKL HD).
2. The following biobanks are members of the BMBH (as of December 31, 2012):
 - Tissue Bank at the National Center for Tumor Diseases (NCT) Heidelberg
 - Liquid Biobank at the National Center for Tumor Diseases (NCT) Heidelberg
 - Tissue Bank for Inflammatory Diseases at the Heidelberg University Hospital (GEZEH)
 - Tissue Bank of the Department for Vascular Surgery at the Heidelberg University Hospital (VBBH)
 - Heidelberg Comprehensive Cardiovascular Biobank (HCCB)
 - PancoBank of the Department for Surgery at the Heidelberg University Hospital
 - Biobank of the German Center for Infection Research (DZIF) - Heidelberg
 - Biobank of the German Center for Lung Research (DZL) – Thoracic Hospital Heidelberg
3. The BMBH management board decides on membership upon receiving a written application. The applicant must contribute a collection of humane biomaterial and accept the rules of procedure as well as the implementation of the rules and infrastructure of the BMBH.

§ 2 Purpose

1. The purposes of the BMBH are the following:
 - A. To support the collection, characterization, registration, archiving and processing of high quality humane biomaterial for research purposes, and to foster scientific projects of the Medical Faculty Heidelberg, the German Cancer Research Center and of all other BMBH member institutions. The BMBH intends to reach this goal by promoting and establishing structural measures, investments, technologies and personnel support, especially of joint and central biobank projects. High priority will be given to supporting the work and cooperations of BMBH biobanks.

- B. To promote quality assured biobanking both in Heidelberg and abroad and to foster the principles of Good Scientific Practice.
- C. To ensure sustainability of biobanking measures through appropriate organization, financing and personnel measures. In particular, the acquisition and the adequate and efficient use of public funding for biobanking will be supported.
- D. To represent all biobanking-related topics in public in the interest of the BMBH member institutions and to achieve an adequate representation of biobanking in scientific works and projects.
- E. To encourage cooperations within the BMBH with other biobanks as well as national and international institutions, initiatives and associations.
- F. To support all other measures that benefit the goals of the BMBH and scientific biobanking.

§ 3 Committees

1. The BMBH is directed by a management board, which is represented by the spokesman or deputy spokesman, respectively. The management board is assisted by the BMBH administration in performing its duties.
2. The BMBH management board consists of the directors of the participating clinical departments or (if the biobank is not part of a clinical department) of the director of the respective biobank, which contributes to the BMBH through biomaterial, infrastructure and expertise, as well as the Dean of the Medical Faculty Heidelberg, the Medical Director of the Heidelberg University Hospital, and the Scientific Director of the German Cancer Research Center. The members of the management board are entitled to be represented temporarily or permanently but revocably by an appointed and expert member of their respective institution.
3. The management board supervises the proper operation of the BMBH. It adopts the rules of procedure and any changes to it (see also § 8), decides on new members, violations against the rules of procedure and sanctions as well as the dissolution of the BMBH (see § 9). The decisions are generally approved by a simple majority, unless the rules of procedure stipulate a different majority. Decisions can only be made under the condition that at least half of the management board members or their representatives are present. Decisions can also be made by written circulation procedure, unless at least one management board member contradicts to this method of decision making.

4. If not stipulated differently, the management board elects a spokesman and a deputy spokesman from his ranks for the period of 3 years. This spokesman summons the management board, chairs the board meetings and represents the BMBH externally in scientific and organizational matters. The spokesman and deputy spokesman may be re-elected.
5. The management board meets regularly, but at least once a year. Members of the BMBH administration take part in the regular board meetings as non-voting members.
6. The administrative director of the BMBH reports to the management board once a year in written form about the progress of the BMBH. Additional reports can be made upon request.
7. The BMBH management board summons a scientific advisory board consisting of recognized scientists with experience in biobanking and advising the BMBH and its management board in all technical and organizational issues. The scientific advisory board must be informed about the progress of the BMBH at least once a year.

§ 4 Use

1. Users of the BMBH are employees of the Medical Faculty Heidelberg or the German Cancer Research Center, or they are employees of other BMBH member institutions.
2. The services and procedures, especially the provision of all kinds of asservated biomaterial, are regulated in the respective user rules of the BMBH member biobanks. The respective user rules have to be made accessible to the BMBH.
3. The disposal of biomaterial and data is coordinated by the BMBH member biobanks upon written application and according to the user rules of the respective biobank. The requirements are a defined scientific project and a corresponding, valid vote by the ethics committee as well as the written consent of the patient or test person. The management of the respective biobank decides on the approval and the procedure of a project in consideration of technical and organizational reasons according to the respective user rules. In the case of refusal of a project, a written explanation has to follow. Participating clinical institutions have priority access to samples submitted by themselves and always have to be informed and asked for a written agreement prior to the approval of a project.
4. After the handover of biomaterial or extractions, the user is responsible for its appropriate handling and use in accordance with all applicable provisions. The management board of the respective biobank decides on the sharing of biomaterial or

extractions with third parties in single cases considering the respective votes of the ethics committee and the patients' consents; the contributing clinical institution's obligation to consult is not affected and needs to be taken into consideration.

§ 5 Financing

1. The BMBH with all participating biobanks is a non-profit institution of the Medical Faculty Heidelberg, the German Cancer Research Center (DKFZ) and the Heidelberg University Hospital (UKL HD). The BMBH and its participating biobanks are entitled to charge an adequate fee for their services. The sale or sharing of
2. collected biomaterial or its derivatives for commercial use is excluded without specific prior authorization.
3. The BMBH may be assigned an adequate personnel, materials and investment budget for its operation and services, which in turn has to be used purposefully.

§ 6 Operating procedures

1. The principal working steps within the BMBH are subject to the principles of Good Laboratory Practice (GLP) and are defined in Standard Operating Procedures (SOPs).
2. The collecting, characterizing, evaluating and processing of humane biomaterial and its extractions for research purposes is always a scientific achievement that has to be considered appropriately in publications and scientific project proposals.
3. All works have to be performed in such a manner that the diagnostic evaluation of the extracted material is not affected.

§ 7 Organization

1. In organizational terms, the BMBH is affiliated to the Institute of Pathology's Department of General Pathology and Pathological Anatomy of the Medical Faculty Heidelberg. The affiliation of the respective BMBH member biobanks needs to be regulated within their respective rules of procedure.
2. The BMBH provides all participating biobanks with administration infrastructure and therefore adequate and sufficient premises are assigned at the Institute of Pathology by the Medical Faculty Heidelberg and the Heidelberg University Hospital. The respective operators are responsible for the necessary basic equipment of the BMBH biobanks, including the access to necessary information complying with the approval situation and the legal provisions or their internal rules of procedure, respectively.

§ 8 Changes to the rules of procedure

The BMBH management board decides on changes to the rules of procedure with a two-thirds majority of their members. Issues concerning the organizational structure of the BMBH are decided by the Medical Faculty Heidelberg in coordination with the NCT Steering Committee and the BMBH management board.

§ 9 Dissolution of the BMBH

1. The dissolution of the BMBH as an institution of the Medical Faculty Heidelberg, the German Cancer Research Center (DKFZ) and the Heidelberg University Hospital (UKL HD) is decided by the BMBH management board in agreement with the Medical Faculty Heidelberg, the Heidelberg University Hospital's (UKL HD) Board of Directors and the Board of Directors of the German Cancer Research Center (DKFZ). The destination of potential facilities and material of the BMBH is decided by the Medical Faculty Heidelberg according to the proposal of the BMBH management board. The participating biobanks are principally independent from dissolution and decide according to their respective rules of procedure.
2. A sale of the BMBH or single parts thereof is explicitly excluded.
3. Biomaterial that cannot be maintained anymore after dissolution of the BMBH must be disposed of according to the applicable provisions.

§ 10 Severability clause

All other conditions that are not listed in the rules of procedure of the BMBH have to be treated appropriately and in the interest of the rules of procedure, its purpose, its operators and the participating biobanks (in order of priority).

Heidelberg, February 20, 2013