PATH Biobank
Sample allocation – „terms & conditions"
Version 1.5

A) Preamble

In order to be able to provide well characterized samples for research, breast cancer patients in Germany took the initiative in 2002 and started with the establishment of a tumour tissue and blood serum bank for Mamma-Ca. The objective of PATH Biobank is to support cancer research with the supply of fresh frozen and FFPE samples.

Since 2004, seven certified German breast centres have been collecting samples of tumour and normal tissue, as well as blood serum, following standard SOPs. Fresh frozen samples are stored at –150°C in the gas phase of liquid nitrogen, FFPE samples are available as well. All relevant data have been collected in PATH's own centrally managed data base.

As of today, more than 12,500 women and men have donated samples and data. Each case is based on *Informed Consent*.

B) This is what PATH Biobank offers

- Samples of tumour tissue, normal tissue and blood serum in „fresh frozen" quality, with a cold ischemia time of maximum 45 minutes.
- Tissue samples with about 3 mm edges, blood serum aliquots of 1ml
- Formalin fixed paraffin embedded samples
- Standard SOPs (for sample collection and processing), as well as regular quality controls in the participating breast centres
- Uniformed, centrally managed data sets for each sample (clinical data, tissue processing information, histopathological and tumour biological data, follow up data concerning therapy, as well as mortality and events)

C) Requirements for obtaining samples

1. Application describing the ongoing and planned research
2. CV of the leading applicant; publication list
3. Scientific rational
4. Description of the processing and analysis of the samples
5. Biometrical/statistical calculations for the amount of samples needed
6. Details of the costs for obtaining the samples (see D)

(points 1 - 5 together as a short exposé, overall 2 – 5 pages)

D) Conditions for obtaining samples

PATH Biobank is not a commercial company, and its Board Members work on a voluntary basis. Nevertheless, there are considerable costs for freezers, data collection, follow up and project management. It is therefore necessary to request a basic compensation which will enable PATH to continue its work with the tumour bank in the years to come.

Below is a list of requirements that should all be met for a cooperation project including the obtaining of samples, as this would be in the sense of this patient-owned tumour bank project. However, depending on the nature and size of the project and the possibilities of the project partners, the implementation of each requirement can still be discussed.

Requirements:

- Options for a financial plan to cover the cost recovery fee for obtaining the samples and data. The compensation is calculated based on nature and quantity of the samples obtained.
- Feedback of research results (e.g. quality parameter of the samples) to PATH Biobank. (Timeframe and nature of reporting to be agreed on for each project.)
- Co-authorship of the PATH staff. Acknowledgement and description of the work of PATH in publications and presentations linked to the research project.
- Contractual agreement on all agreed terms and conditions for obtaining samples with in a material transfer agreement
- Comments and explanations on the handling and protection of personal data

E) Review process and communication

- Applications should be submitted by e-mail to info@stiftungpath.org Further details can be obtained from Dr. Franziska Sommermeyer, e-mail sommermeyer(at)path-biobank.org, and Dr. Kathrin Lerchl, e-mail: lerchl(at)path-biobank.org .
- The cost recovery fee for providing the samples can be calculated before the application is submitted, if the required quantity of samples and data is provided.
- Peer review, final decision will be made by the Board of the PATH Biobank, possibly following a consultation with its Board of Trustees. The decision making progress should not take longer than 1 month.