

## **PATH Foundation**

### **Obtaining samples – „terms & conditions“**

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#### **A) Preamble**

In order to be able to provide well characterized samples for research, breast cancer patients in Germany took the initiative in 2001 and started with the establishment of a tumour tissue and blood serum bank for Mamma-Ca. The objective of the PATH Foundation is to support cancer research with the supply of fresh samples. In addition, PATH freezes a sample of tumour tissue and blood serum of each patient that can be obtained by her at any time. The freezing and storage of the sample is free of charge

Since 2004, seven certified German breast centres have been collecting samples of tumour and normal tissue, as well as blood serum, following standard SOPs. Samples are stored at  $-150^{\circ}\text{C}$  („fresh frozen“ quality). All relevant data have been collected and successively complemented with follow up data in PATH's own data base.

As of today, samples from over 4000 women and men have been collected and stored. Each case is based on *Informed Consent*. In the year 2011, a large part of this collection will have been followed up by 5 years in average.

#### **B) This is what the PATH Foundation 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 4 mm edges, blood serum aliquots of 1ml
- Over 4000 tumour tissue samples from about 1900 individuals diagnosed with primary breast cancer; 9000 blood serum aliquots from about 3000 women
- 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 (one page)
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)

## **D) Requirements and conditions for obtaining samples**

The PATH Foundation 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 compensation for obtaining the samples and data. It is recommended to include these costs right from the beginning in the application for external fund-raising (DFG, DKH, etc.). The compensation is calculated based on nature and quantity of the samples obtained.
- Feedback of research results to the PATH Foundation. (Timeframe and nature of reporting to be agreed for each project.)
- Co-authorship of the PATH Foundation and all centres that are involved in the sample collection. 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.

## **E) Review process and communication**

- Applications should be submitted by e-mail to [info@stiftungpath.org](mailto:info@stiftungpath.org) or by mail to Stiftung PATH, Schäfflarnstr. 62, 81371 München. Further details can be obtained from the project manager Tobias Anzeneder, e-mail [anzeneder@stiftungpath.org](mailto:anzeneder@stiftungpath.org), telephone: +49 – (0)89–78067848.
- The amount of compensation for providing the samples can be calculated before the application is submitted, if the required quantity of samples and data is provided.
- Peer review by three experts (two experts from PATH's scientific panel, as well as one external expert, who has also been engaged in other peer review processes, e.g. DFG). It will take up to 2 months to evaluate an application, provided it was complete when submitted.
- The final decision will be made by the Board of the PATH Foundation, possibly following a consultation with its Board of Trustees. The decision making progress should not take longer than 1 month.
- The final decision whether or not the requested samples will be provided by PATH to the applicant will follow in writing.