Informed Consent in Biobanking

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My story

- My doctors brought in the big guns: The stronger the treatment, the better.
- Molecular tumor biology was in its infancy
- I would have gladly done without CTX
- I have seen many women lose their battle
The modern Patient

- Democratization of knowledge via the internet
- WWW instead of Yellow-Press-“News”
- More information and higher demands
- „Breast cancer-universities“
- Shared decision-making
- Modern, informed patient has faith in molecular biology research and expects tailored therapies

Prof. Dr. Axel Ullrich, PATH’s spin doctor „Having tumor tissue samples in the freezer, means having power.“
BUSEN. TITTIS. MELONEN.
DINGER. KNOSPEN. BÄLLE.
MÖPSE. GLOCKEN.
BRÜSTE.

KREBS MACHT KEINEN UNTERSCHIED.
KENNEN SIE IHR RISIKO?
Informationen unter: www.mamzone.de
Since 2002, PATH has been:

- A charitable foundation
- A patient-driven organization, established by members of the breast cancer union „mamazone e.V.“
- A patient-driven biobank for breast cancer
- A joint-venture of doctors, scientists and patients
- A supporter and resource for cancer research
A long way...

- Founded in 2002. First deep freezer 2004 in Augsburg
- Meanwhile work on legal (contracts) and technical basics (SOPs)
- Search for new hospitals, negotiations with gynecologists and pathologists
- Work on a patients’ information and informed consent (expert advice e.g. by Prof. Taupitz)
- Review by ethics committee of University Bonn
- Building a data base and a security concept
- 2004 – 2007 six additional storage facilities
**PATH’s goals**

- Support of cancer research at universities and industry by providing biomaterial and data
- Collection of valuable follow-up information
- Biobanking according to high ethical and technical standards
- Additional storage of samples for the patient is free of charge
- High data security
- No profit, but cost recovery fee
PATH’s results

- Biomaterial in the biobank:
  - Tumor tissue
  - Normal tumor-adjacent tissue
  - Blood serum

- All samples in fresh frozen-quality
  - In the gas phase of liquid nitrogen
PATH’s results

- Number of donors: 8315
- Tumor samples: 4817
- Normal tissue samples: 5143
- Serum samples: 7598
PATH’s informed consent

- Individual patient information and education in pre-surgical talk
- Comprehensive written information (1)
- Clear consent form (2)
- Folder for the patient, including (1+2) and a leaflet
- Additional information offered via
  - Internet
  - Telephone
  - E-mail
PATH’s informed consent

• Informed consent material and process is reviewed by
  ➢ Ethics committee/IRB
  ➢ Medical lawyer
  ➢ State privacy officer

• Key issues:
  ➢ Right of withdrawal, anytime
  ➢ Data protection via “pseudonymisation”
  ➢ Broad consent (cancer research)
  ➢ Timely unlimited storage
  ➢ Transfer of property to PATH
“Ongoing” consent

- Sample donors receive yearly PATH-Newsletter
  - News about PATH Biobank
  - Latest information from cancer conferences
  - Introduction of projects and researches using PATH samples
  - Only ten to twenty persons withdraw per issue

- Transparency via the internet:
  - Projects using PATH samples are stated
  - Publication list is available
    - www.path-biobank.org/index.php/en/research-projects
Informed consent “state of the art”

- Template by “Arbeitskreis medizinische Ethik-Kommissionen in Deutschland”:

- Status quo in the German Biobanking community

Informed consent in discussion

- How will the samples/data be used? What kind of analysis is planned?
  - Intensive information for e.g. whole genome analysis
  - Communication of incidental findings?! 

- Who will use the samples?
  - Categories of third parties should be named

- Where will the samples be used?
  - Other data protection standards in different countries
Informed consent – re-consent

- In a pilot study PATH re-contacted patients explaining genome-wide association studies
- PATH asked for consent to this kind of research
- Summary of results:

![Pie chart showing consent status: deceased 7, consent after 1 letter 11, address unknown 2, contact refused 1, no reply 3, consent after 2 letters 4, consent after 3 letters 3.]

Deceased 7
Address unknown 2
Contact refused 1
No reply 3
Consent after 2 letters 4
Consent after 3 letters 3
Consent after 1 letter 11
Informed consent – dynamic consent

- “Methods for involving participants have not kept pace with changes in research capability”
- “Information is shared digitally at the global level”
- “Informed consent remains static, paper-based and organised around national boundaries and legal frameworks”

Quotes from Kaye et al. (2015)
Informed consent – dynamic consent

• “Dynamic consent is a concept that offers a new approach to consent”
• „A personalised, digital communication interface is provided that connects researchers and participants“
• „Participants are placed at the heart of decision making“
• „In addition to improving transparency and public trust, this system enables more efficient participant recontact“

PATH would like to thank all patients for sharing their tissue and data and all clinicians for supporting PATH Biobank
Dr. Anzeneder contributed to this presentation