Tissue Bank of the National Center of Tumor Diseases (NCT) Heidelberg

At the Institute of Pathology, University Hospital Heidelberg

PD Dr. med. Esther Herpel Leiterin der Gewebebank des NCT



NATIONALES CENTRUM FÜR TUMORERKRANKUNGEN HEIDELBERG

getragen von:

Deutsches Krebsforschungszentrum Universitätsklinikum Heidelberg Thoraxklinik-Heidelberg Deutsche Krebshilfe

- Structural Decisions
- Ethical Aspects and Data Protection
- Finances and Sustainability
- Sampling and Platform Activities
- Project Management
- Quality Management and Accreditation
- Parameters of Performance and Statistics
- Interaction of Tissue Banks





Aims

- Central and comprehensive tissue bank structure
- Research not collective-orientated: ,Making research possible
- Comprehensive ethical/legal frame
- Quality assessment: ,Good scientific practice'; quality management
- Integration of clinical and pathological experts; support of CCC/NCTconcept; role model
- Technology platform and development



Tasks

- Pro- und retrospective collection of tissues; optimal scientific use of tissues
- Compilation of tissue collectives, links to clinical data (Data Pool)
- Technology-platform (Multi-Tissue Arrays, Virtual Microscopy; IHC)
- Quality management (controls [good scientific practice], accreditation)
- Project management (broker funktion; management; training)



Structural Association

Affiliation

Section of the NCT

Operators

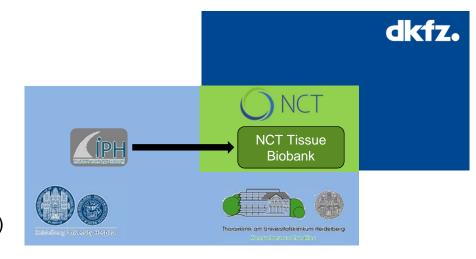
University Hospital Heidelberg German Cancer Research Center (DKFZ) Thoracic Hospital Heidelberg



Institute of Pathology, University Hospital Heidelberg

Association

Biomaterialbank Heidelberg (BMBH)





Participating Units:

University Hospital Heidelberg

- Pathology
- Gynaecology
- Haematology (Plasmacytoma)
- ENT
- Neurosurgery
- Orthopedics
- Urology
- Visceral Surgery
- ZMK

German Cancer Research Center

Thoracic Hospital Heidelberg Rohrbach



Regulatory Activities

- Standing orders (2005)
- Affiliation, Operation (2005)
- Fixed Personel and hardware budget (2005)
- Standard Operating Procedures (2005-7)
- Quality Management (since 2006)
- Accreditation DIN/ISO 17020 (since 2009)



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Ethical/Legal Issues

- Review of ethical issues
 - Comprehensive ethical vote (2005; project independent)
 - Open use of retrospective tissue collective (2005)
- Informed consent
 - Uniform informed consent form (2006)
 - Hospital contract (2009) (automatic negative information)
 - Eigenforschungsvorbehalt (BW)
- External/Research foundations
 - Acceptance by DFG, Krebshilfe (2006)
- Data safety issues
 - Access regulations
 - Pseudonymisation
 - Data safety rules (Pis, Standing orders)
 - Data safety reviews



Biobank - Safety Concept

Pseudonymisation

- Coded for user
- Can be broken by tissue bank
- Separated data banks and –storage
- Admission control
- Regulations of standing orders
- Instructions of personel
- Material Transfer Agreement (Instruction user)



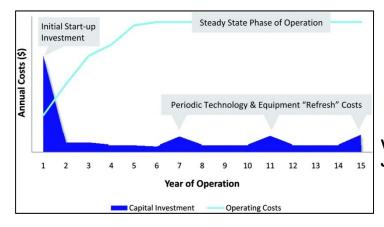
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- Future Directions





Sustainability

- Key issue of all tissue banks; value increases with time!
- Should be mandatory ab initio for all tissue banks/collectives!
 Mostly unsolved!
- Aspects (financial and organisational)
 - Sustained Financing
 - Governing Institution; Accession Rules
 - Policy of Termination



Vaught J et al. J Natl Cancer Inst Monogr 2011;2011:24-31



Financing

- Permanent budget by NCT
- Free service for participants
- Add-on funding
 - Pathology
 - Grant participation (core functions)
 - Special fees (TMAs)



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Paraffin Tissues

- Paraffin archive, Institute of Pathology
- >30y, RT, organized, designated rooms
- 16y full searchable (IT)
- Specified ethical vote (Institute of Pathology)
- Project-based access for Tissue Bank (contract)
- Primary blocks remain part of Tissue Bank (fully retrieveable)



Storage Conditions Frozen tissues

- Specified -80° C freezers
- Climatized freezer rooms
- Regular daytime check (7 d; documented)
- Individual freezer alarm
- 24 h automatic centralized alarm system for all freezers
- Designated on-call person (schedule)
- 2 stand-by running freezer; -20° C room
- Emergency electricity supply



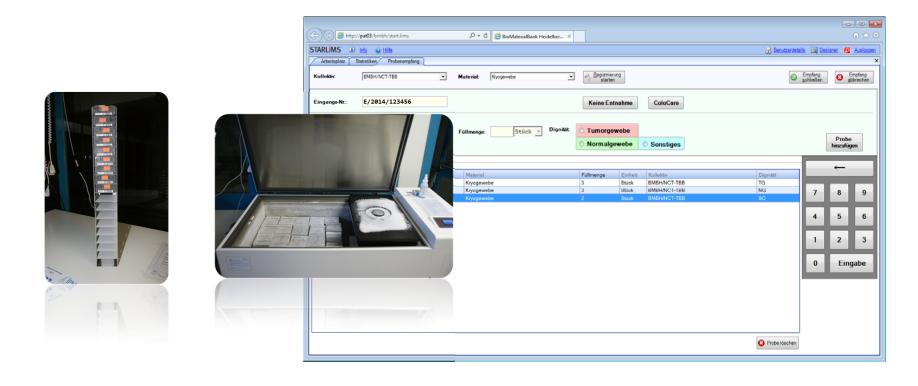
Storage Locations

- Institute of Pathology (Core Unit)
- Decentralized Facilities
 - Thoracic Hospital/Thoracic Pathology
 - Neuropathology/Neurosurgery
 - Orthopedics





STARLIMS-Modul Scan/ Reception



- Fast registration of single samples via handheld scanners
- Automatic allocation of collective, material, patient-ID, filling volume
- Integrated error checking via regular terms
- Controlling streamlined for touchscreen



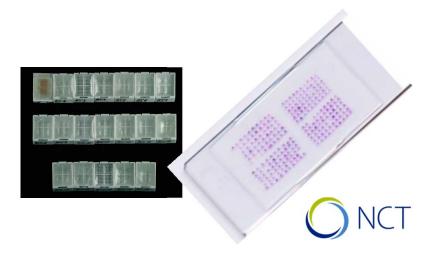
Central Laboratories NCT Tissue Bank

- Paraffin- and frozen sections
- HE and special stains
- Multi-Tissue-Arrays (manual and automated)
- Immunohistology (automated)
- Registration and storage of frozen tissues
- Compilation of paraffin tissue collectives
- Reference service and training



Heidelberg TMA Facility at NCT Tissue Bank

- Single location core facility
- Instrumentation (2 manual; 1 semiautomated)
- Lab, archiving, trained personel
- >150 TMAs; ~300 projects
- Documentation, image analysis, bioinformatics (VM platform)
- Collective oriented (clin. data, epidem. trials)
- Consortional center function (natl./international trials)
- Central TMA-management function; linked to VM core
- Future: automated work-flow



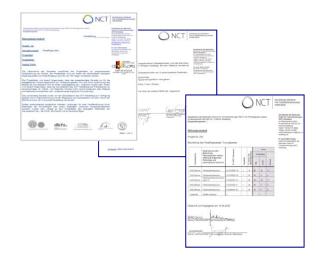
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Quality Management

Structural components	Processual/scientific components			
1. Organisation/Structure	Tissue characterisation and quality control (entry/exit control)			
2. Regulations	2. Project evaluation and management			
3. Internal and external review system	3. Project tracking and documentation			





SOPs of NCT Tissue Bank

Structural SOPs	Scientific/Procedural SOPs				
Responsibilities of leadership	Patient consent/documentation				
Definition of politics	Entry controls of fresh tissues and other materials by pathologists				
Definition of aims	Asservation of fresh tissues				
Organisation structure	Storage of fresh frozen tissues				
Description of functions	Processing of tissues/materials				
Training schedules	Project coordination				
Training plan	Exit control of requested material including expert pathological-anatomical report				
Withdrawal of consent	2 Prozess-und Prüfmittel 2 Patientenaufklärung_Dokumentat. 3 Stempel Gewebebank 4 Stempel Gewebebank 5 Ho Versorgung FG nach 17.00 Uhr 5 Truhenmessung Temperatur 5 m Rückführung auf Messnormale 7 Jo Anschreiben Patient kein Kryom 7 Jo Anschreiben Patient kein Kryom 7 Jo Anschreiben Patient kein Kryom 7 Jo Anforderungsbogen Kryogewebe 8 Jo Bearbeitung Kryogewebe 9 Jo Bearbeitung Kryogewebe 10 Jo Übergabeprotokoll_Kryogewebe 10 Jo Übergabeprotokoll Kryogewebe 11 Lo Umlaufverfahren Beirat Kryogew 12 Ju Übergabeprotokoll Thoraxklinik 13 Anforderungsbogen Kryogewebe 14 Bearbeitung Paraffinge 15 Projektanforderungen NCT TMA 16 Ju Verlage Befund Tumor 17 Ju Vorlage Befund Tumor 18 Gerätebuch Prozessmittel 19 Ju Wechsel Alkohol, Xylol 10 Ju Sammelsystem Entsorung				

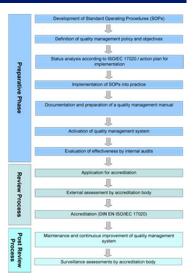
29 Dateneingabe und -abfrage in ST...

26d Gelber Schein zur Annahme von... 26e Gelber Schein zur Annahme von ... 27 Verpackung_Versand



Accreditation NCT Tissue Bank

- Since 2005 SOPs, 1st generation
- Since 2006 SOPs 2nd generation
- Since 2006 defined quality management system
- Request to Sector Comitee of DAkkS by NCT Tissue Bank (2007)
- General approval by DAkkS (2007)
- Application of NCT Tissue bank for Accredition (2008)
- Inspection (November/December 2008) by Deutsche Akkreditierungsstelle according to DIN EN ISO/IEC 17020:2004
- Formal accredition (04/09)
- Official Audit and extension of accreditation (6/10)
- Reaccreditation 01/2014







Quality Tissue Materials

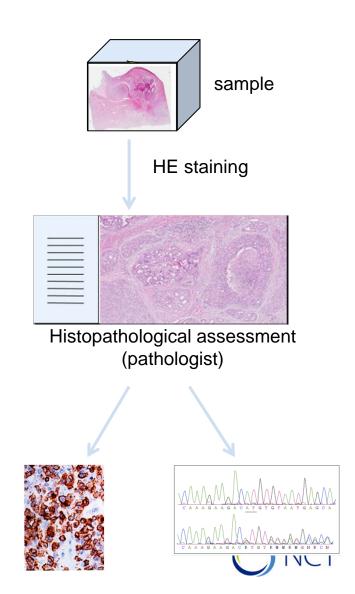
- >>50% of studies using homogenised human tissue derivatives relies on insufficiently characterized/ducumented starting material and is thus absolutely unreliable (→ Perren Nature 2011)
 - > Expert-evaluation (diagnosis, quality, composition of collective)
 - > Trial specific parameters
 - > Standardized entry- and exit-controls
 - Standard reporting and documentation
 - Advice
- Good scientific practice in pre-experimental tissue assessment and selection is the decisive basis of work with human tissues
- Significant scientific contribution





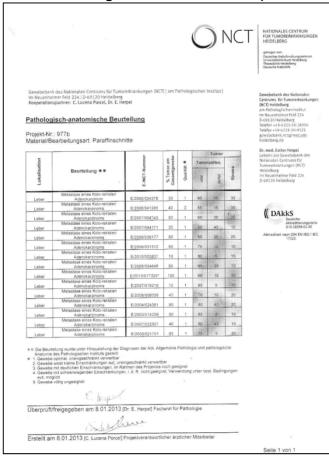
Tissue quality

- Processing of material according to scientific questions
- Projects need different quality
 - Type of material (FFPE vs. Fresh Frozen)
 - Immunhistochemistry vs. Homogenisation
- Provision of pathological findings (exit control)
 = quality control
- Compilation of a delivery protocol which comprises a MTA (instructions for the proper use of samples, citation rules for publishing, etc.)



Tissue quality

Pathological-anatomical report







Continual improvement – "Error/fault" management

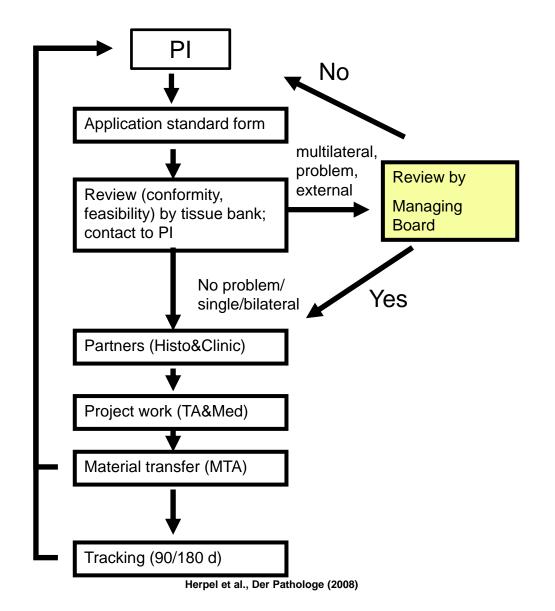
- Active error/fault management
- Registration of faults
- Tracking: registration of criticism and customer satisfaction
- Implementation of corrective actions
- Training courses



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NCT Tissue Bank - Project management + Tracking



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Projekt (Titel, Kurzbeschreibung) *						PD Dr. med. Esther Herpel Leiterin der Gewebebank des Nationalen Centrums für Tumorerkrankungen (NCT) Heidelberg Im Neuenheimer Feld 224
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Kooperationspartner	Datum		ehmigung:	Klir	nik:	-
Bemerkungen						



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Project status

- Projects: 1568 (02/2015)
- Completion rate: 95%
- Multi-Tissue-Arrays: >130
- Frozens: 30.000 (without aliquots)
- Access to paraffin archive (>500.000)

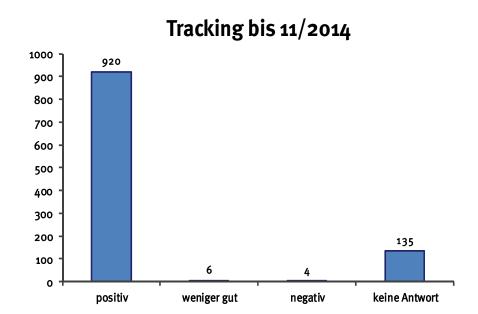


Statistics

 Publications with tissue material until 2014:

 Participation at various conferences (poster, presentations, chairman, expert activities)

Feedback of project leaders





Consent – a Problem?

- Analysis admission contract (2015): 1,2% rejection
- Analysis tissue bank (2015): 0.98% rejection
- Less than 4 post hoc withdrawal of consent

Very high consent rate



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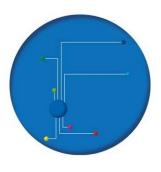


Consortional Projects

- Local: BMBH
- Population-based national and international epidemiological studies (DACHS, IMPACT, EPIC (colon/pancreas Germany), ColoCare, Helmholtz-Cohort)
- National Research Consortia (KOSAR (Sarcoma); SFB/TRR77 (HCC), SFB 1118 (diabetes))
- Clinical Trials (e.g. INNOVATION)



Participation in German Centers for Health Research (DZG)



Prof. Dr. Peter Schirmacher PD Dr. Esther Herpel Dr. Melanie Herzog

<u>DKTK</u>



Dr. Tanja Weiss HCB → BMBH





Prof. Dr. Peter Schirmacher

Dr. Felix Lasitschka

Dr. Lotte Schmidt



Dr. Thomas Muley
Biobank Thoraxklinik
→ BMBH

National cohort (NatKo)



Pathologie

A Pathologie Kooperation NCT NCT-Gewebebank

Notfall - Emergency

Disclaimer

Gewebebank

Informationen für Patienten

Informationen zur Transparenz gemäß Ethikrat

Rechtsform, Datenschutz, Aufsichtsbehörden

Zuständigkeiten

Ansprechpartner und vertiefende Informationen

Regeln und Zwecke

Aktivitäten der Biobank

Maßnahmen zur Qualitätssicherung

Technologieplattform

Tissue-Micro-Arrays **Immunhistologische** Färbungen

Extraktionsverfahren

Referenz- und Trainingsleistungen

Mitarbeiter/Beirat

Kontakt

Downloads

Links

AG der Gewebebanken der Comprehensive Cancer

Aktivitäten der Gewebebank

Kongresse und Workshops

Publikationen

Eingeladene Seminare

Veranstaltungen

Drittmittelanträge

Internationale Aktivitäten

Nationale Aktivitäten

Qualitätsmanagement

NCT-Gewebebank

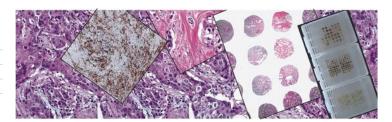
Die Gewebebank ist eine Einrichtung des Nationalen Centrums für Tumorerkrankungen (NCT) Heidelberg unter der Schirmherrschaft der Medizinischen Fakultät der Universität Heidelberg und des Deutschen Krebsforschungszentrums (DKFZ).

Zweck der Gewebebank ist das Sammeln, Charakterisieren, Registrieren, Archivieren und Aufbereiten von Geweben und Gewebsextrakten (z. B. in Tissue-Micro-Arrays) in hoher Qualität für wissenschaftliche Untersuchungen im Rahmen der Tumorforschung.

Die Gewebebank unterstützt biomedizinische, wissenschaftliche Projekte der Medizinischen Fakultät der Universität Heidelberg, des Deutschen Krebsforschungszentrums, der Thoraxklinik Heidelberg-Rohrbach, der Orthopädischen Universitätsklinik Heidelberg und aller sonstigen Einrichtungen, die Mitglied des NCT Heidelbergs sind oder zur Gewebebank des NCT beitragen.

Daher besteht für Mitarbeiter der oben genannten Gruppen die Möglichkeit, Gewebeproben und Paraffinschnitte von Multi-Tissue-Arrays aus der Gewebebank unter Darstellung des Verwendungszweckes zu erhalten, um diese im Rahmen von wissenschaftlichen Fragestellungen untersuchen zu können.

Entsprechende Anträge finden Sie unter Downloads.





» Nationales Centrum für Tumorerkrankungen (NCT)



Homepage: <u>www.nct-gewebebank.de</u> Email: gewebebank.nct@med.uni-heidelberg.de

