

Biobanking for Precision Medicine

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Biobanking: The Fuel of Precision Medicine



Global Market Size - Human Biological Samples Market



Projected Growth of Precision Medicine



Sources: Supplier Interaction, Nature Biotechnology, Asterand Investor Forum

Biobanking isn't Simple

- Numerous parties involved with different goals/incentives
- Complex infrastructure for procurement and handling of biosamples
- Need for Regulatory compliance, SOPs
- Challenges of linkage to clinical data
- Non-transparent and confusing processes work around often used to circumvent issues

Biobanking isn't Cheap

A Plan for Academic Biobank Solvency–Leveraging Resources and Applying Business Processes to Improve Sustainability

Diane Uzarski, D.N.P., M.P.H., R.N.¹, James Burke, M.D., Ph.D.², Barbara Turner, Ph.D., R.N., F.A.A.N.³, James Vroom, D.H.A., F.A.C.H.E[®], C.P.A.³, and Nancy Short, Dr.P.H., M.B.A., R.N.³

Abstract

Researcher-initiated biobanks based at academic institutions contribute valuable biomarker and translational research advances to medicine. With many legacy banks once supported by federal funding, reductions in fiscal support threaten the future of existing and new biobanks. When the Brain Bank at Duke University's Bryan Alzheimer's Disease Center (ADRC) faced a funding crisis, a collaborative, multidisciplinary team embarked on a 2-year biobank sustainability project utilizing a comprehensive business strategy, dedicated project management, and a systems approach involving many Duke University entities. By synthesizing and applying existing knowledge, Duke Translational Medicine Institute created and launched a business model that can be adjusted and applied to legacy and start-up academic biobanks. This model provides a path to identify new funding mechanisms, while also emphasizing improved communication, business development, and a focus on collaborating with industry to improve access to biospecimens. Benchmarks for short-term Brain Bank stabilization have been successfully attained, and the evaluation of long-term sustainability metrics is ongoing. Clin Trans Sci 2015; Volume 8: 553–557

Increasing Biobank Utility and Value

- Improve quality and reduce cost
- Be responsive to investigator (customer) needs
- Develop new processes (such as plasma for cfDNA), organoids
- Collaborate with industry several banks use services such as BioServe and ReproCell
- Rename Health Sciences Tissue Bank (HSTB) to Pitt Biospecimen Core (PBC) for better marketing

Health Sciences Core Research Facilities **PITT BIOSPECIMEN CORE**

Central support for University of Pittsburgh research programs needing tissue materials for research from patients seen at UPMC

- Prospective tissue and fluid collection and banking
- Honest broker and IRB services, Research histology services
- Active since 1991
- ~65,000 patient visits with ~800,000 biosamples

PRODUCT TYPE	SPECIMENS	
BLOOD	265383	~75% cancer
URINE	35577	
OTHER BIOLOGICAL FLUIDS	3393	
SOLID TISSUES	102051	CAP
NORMAL TISSUE	26668	

Value of having a common patient (BIOS) and biosample (TP) identifier

- Permanent database that isn't dependent upon a grant or specific lab person
- Project tracking system allows all communication with Biobank to be recorded regarding biosamples
- BIOS allows multiple TPs e.g. longitudinal blood collection
- TP number allows simple linkage to cancer registry using honest broker
- TP allows multiple investigators to work on the same biosample and share data/knowledge

Provenance/Governance

- Investigators own their biosamples, PBC is just a bank
- Investigator banks samples under consent and an IRB protocol
- Requests for tissue notify the IRB owner
- Governance by PBC regulatory staff
- •Tissue Use Committee (TUC) oversight

Most abundant organs

ТҮРЕ	CASES	WITH BLOOD	WITH TUMOR+NORMAL	TOTAL SAMPLES	т	YPE			CASES		SAMPLES		
Breast	6166	750	2839	13321	P	neumonia			197		2748		
Ovary	5946	1565	613	16625	E	mphysema			116		1779		
Colon	3283	1175	780	7488	C	Diverticulitis			98		178		
Prostate Gland	2746	1937	11	18552	C	Crohns			216		399		
Uterus	2157	370	80	2567	C	Diverticulosis			112		239		
Lung	1786	45	308	11585	В	Bronchiectasis			55		850		
Kidney	1775	419	253	5893	C	Colitis			169		278		
Search Cart Items							© 58:56 Lee, Adrian V . Logout						
* Source: Lung • Medium: frozen • Diagnosis: •													
Check All	<u>Unc</u> h	eck All	Total Result	s Rows: 1	158	r			Add to	Cart	View Cart (0)		
	#	Subject Name		Source			Collection Date	BarCode	Medium	Avl. Vol	Req. Vol		
HB107	7	BIOS3309		Lung LLL			02/2005	S00008684B	frozen	0.19 GM	0.19		
HB107	7	BIOS3309		Lung LLL			02/2005	S00008686D	frozen	0.14 GM	0.14		
TP10-43	35	BIOS8973	Lu	Lung LUNG - LOWER LOBE			03/2010	MW00046636	frozen	0.13 GM	0.13		
TP09-75	55	BIOS12627	Lu				05/2009	mw00036394	frozen	0.13 GM	0.13		
TP10-10	80	BIOS12027				08/2010	MW00036395	frozen	0.07 GM	0.09			
TP10-10	80	BIOS15120		Lung RIGHT LUNG			08/2010	MW00044700	frozen	0.05 GM	0.05		

Most abundant non-cancerous diseases

The Cancer Genome Atlas (TCGA)



University of Pittsburgh:

- **# 1** contributor in **breast** and **prostate**
- # 2 contributor in head and neck and renal
- # 3 contributor in ovarian
- # 4 contributor in melanoma and bladder

Frozen vs FFPE

- Bank initially focused on freezing biosamples
- Frozen samples can be used under the PBC IRB and thus don't require a new IRB submission
- Recent increase in use of FFPE
- Most recent movement to fresh disbursement

Linking Clinical Data and Tissue

• BIOS is linked to TIES

Resource

A Federated Network for Translational Cancer Research Using Clinical Data and Biospecimens 😰

Rebecca S. Jacobson¹, Michael J. Becich¹, Roni J. Bollag², Girish Chavan¹, Julia Corrigan¹, Rajiv Dhir¹, Michael D. Feldman³, Carmelo Gaudioso⁴, Elizabeth Legowski¹, Nita J. Maihle², Kevin Mitchell¹, Monica Murphy⁴, Mayurapriyan Sakthivel⁴, Eugene Tseytlin¹, and JoEllen Weaver³

Rebecca S. Jacobson et al. Cancer Res 2015;75:5194-5201

Cancer

Research

- TIES linked to Cancer Registry
- Link BIOS to EMR



Unique Rapid Autopsy Program



Hartmaier R et al Ann Oncol. 2018 Apr 1;29(4):872-880

New Processes e.g. cfDNA and Organoids











Enabling Personalized Care

The Institute for Precision Medicine (IPM) Announce Pilot Project Funding in

Support of Human Tissue Requests from the Pitt Biospecimen Core (PBC)

The Pitt Biospecimen Core Partners in Research at the Hillman

Paul Wood, MS Assistant Director for Core Facilities Office of Research, Health Sciences



Topics and Goals for Today

- Update on structure, quality, and cost
- Explanation of fiscal structure: Income and expenses
- Model of interactions with programs and PIs
- Next steps for the tissue banking community to keep abreast of changing needs.

I want you to walk away with an understanding of how the Pitt Biospecimen Core (PBC) operates and how it has changed in the recent past. In particular, I will describe how costs are shared based on the role the PBC plays in each project and how to get this information for your project.

Health Science Core Research Facilities – Organizational Chart



PBC Function and Purpose

- Procure, bank and disburse human biological specimens
- Honest broker and case annotation
- IRB protocol submission assistance
- Research histology
- Clinical trials
- Add functions based on PI need & PBC capabilities

The purpose of the PBC is to foster excellent research using human biospecimens at the University of Pittsburgh. Our objective is to simplify and streamline the process for procurement and distribution of human bio-specimens and to provide pathology support services.

What is the PBC

- 5,600 sqft of total space at UPMC and Pitt
- Presence at five collection sites: Magee, Presbyterian, Shadyside, Passavant, Children's Hospital (coming soon)
- 6 freezer rooms at 4 sites
 - 49 mechanical -80C freezers (empty backup at each site)
 - 7 LN2 Dewars
- Nearly 800,000 biological samples from ~65,000 patient encounters (~75% Cancer related)
- UPMC server space and LIMS management
 - Biospecimen Inventory and Operating System (BIOS)
 - Project Management Request Tool

Today's Pitt Biospecimen Core

- Expertise
 - Scientific Director Rajiv Dhir; MD, MBA
 - Operations Director Susan Kelly; M. Ed., QLS^{CM ASCP}
 - Quality Manager Luke Wiehagen; MBA
 - Project Manager/IRB expert Nicole Pistorius; BA, CIP
 - Certified Histologist Tony Green; HT(ASCP), AS



Today's Pitt Biospecimen Core

- Centralization
 - Fully behind the UPMC firewall
 - Honest Broker system seamlessly interfaces with UPMC
 - Honest Broker manages Research IDs (TP#)
 - EMPI number associated with every case
 - Linkages to Clinical Data
 - Track multiple encounters, same patient
- Scalability- Projects ramp up and down
 - Hiring and supervision by PBC
 - Trained staff and backups
 - BIOS Biospecimen Inventory Operating System

Today's Pitt Biospecimen Core

- Efficiency
 - Quality program and operations serve many PIs
 - Staffing for many projects with varying collection schedules
 - Billing and subaccount management by HSCRF Admin
- Transparency and accountability
 - Project Manager provides centralized contact
 - Project Management Request Tool-requests/response tracking
 - Enhanced web presence
 - Structured project and processing fees
 - Media Labs Document Management- SOPs
 - Annual staff competency training
 - College of American Pathologists (CAP) Accreditation

Two kinds of cost recovery

- Time and Materials
 - Research Grant Mechanism
 - e.g. Collection, processing, insertion into storage, data entry
- Recharge (Fee-for-Service)
 - Defined by cost model and charged by invoice
 - e.g. Sample distribution, Sample QC Histology

Scenario #1 – Investigator Collection

Collect 100 cases/year

- 1 Vacutainer Whole blood
 - Plasma and blood aliquots
- Bank materials

Time and materials

- budget ~\$8,500
 - .15 FTE
 - Supplies

Scenario #2 – Investigator Collection

Collect 100 cases/year

- Tissue
- Plasma
- Urine
- Bank materials

Time and materials

- budget ~\$14,000
 - .25 FTE
 - Supplies

Scenario #3 – Investigator Collection

- Collect 100 cases/year
 - Tissue
 - Plasma
 - Urine
- Bank materials

- Time and materials budget ~\$14,000
 - .25 FTE
 - Supplies



Storage

\$1,575/full freezer/year

Scenario #4 – Disbursement Request for PBC Collection

 Collection – 1000's of cases with samples from priority Annual costs paid through organ systems and diseases institutional subsidy.

- Criteria Search qualify
- Disburse 25 samples
- QC (Cut, stain, review)

Recharge budget = \$2,355\$105 25 X \$50 = \$1250 25 X \$40 = \$1000

How does a researcher find out how much services cost?

- Service, pricing, contact information & more at Web site
- Need help to define your project and receive cost info?
 - Histology only Contact Histology Supervisor: Tony Green
 - All other Contact the Project Manager: Nicole Pistorius
- Electronic communication
 - Email: Provide project details and receive a quotation
 - Log into the Project Management Tool from the website link

Once we have a scope of work defined, you will receive a quotation for recharge services and a cost estimate for Time and Materials. One project may include both.

Contact information

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www.PittBiospecimenCore.pitt.edu