The Ohio BioRepository: A Community Hospital Focused Tissue Repository

Windows of the Future
March 7, 2006

Bill Tacon, Ph.D.

www.ohiobiorepository.org
Omeris

- Founded in 1986 as the Edison BioTechnology Center, Omeris is a non-profit organization designed to build and accelerate bioscience industry, research, and education in Ohio
Omeris’ Dual Role

• Statewide public-private economic membership organization for biosciences
• Business Development via 4 regional bioscience incubators
Omeris’ Bioscience Incubators Partners

2003 Incubator of the Year - USA

www.biostart.org

www.biocolumbus.com

www.bioenterprise.com

www.ohiou.edu/biotech

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What do the Bioscience Incubator Partners do?

- **Collaborations** with universities, established companies, and start-up companies; national and international collaborations
- **Business development** to help established and startup companies make contacts and pursue success
- **Management support** for startup companies, “portable executives” until the company operates on its own
- **Professional Services** referrals to attorneys, accountants, and others who understand the technology, the startup company environment, international business
- **Access to Capital** helping startups find investors, and helping investors find companies to invest in
Omeris’ Role

- Advocacy and Visibility
- Marketing / Networking
  - BIO
  - BioOhio
  - Regional events
- Trade Missions
- *State and National Caliber Projects*
- International and National Attraction
Why a Tissue Repository?
Tissue Bottle-neck

• Availability of validated human tissue & associated patient/clinical data is creating a research bottle-neck

• Why?
Junk in, junk out.

TISSUES

gene - proteome - disease - proteome - gene

disease - disease - disease - disease - disease
Need Recognized at a Federal Level

• AACR Annual Meeting, Washington, DC
  NCI – July 11, 2003 – Dr. von Eschenbach
  – Will develop a National Biospecimen Network (NBN)
    • Access to tissues and other biological specimens
    • Collection
    • Dissemination
    • Associated clinical data (data management)
    • New research and translational findings
NBN Blueprint

- Why the NBN
- Biospecimen and data collection & distribution
- Bioinformatics & data management
- Governance

September 2003
CHTN - A well established tissue collection network
National Cancer Institute’s Cooperative Human Tissue Network

- The Ohio State University Medical Center
- The University of Alabama at Birmingham
- University of Pennsylvania Medical Center
- University of Virginia Health System
- Vanderbilt University Medical Center
- Children’s Research Institute
- Case Western Reserve University (1992-2000)
Human Tissue for Research

- Malignant, benign, diseased and normal
- Fresh, frozen, fixed
- Academic and commercial investigators
- Requires IRB approval from investigator’s institution
- Investigator Agreement
- Data Use Agreement (HIPAA)
- Tissue sourced from major medical centers
www.ohiobiorepository.org
Our Intent (in 2003)

• Omeris to establish a biorepository, which could also serve as a regional component to the NBN
• Start with cancer, but expand to include all disease types
• Leverage Ohio’s Academic, Commercial, Hospital and Informatics networks
• Focus on Ohio’s community hospitals which serve ~85% of the cancer population
• Other states, e.g. Pennsylvania, Georgia, Arizona, are already on this path
OBR - Structure

- Ohio BioRepository (OBR) established as an independent operating entity of Omeris
- OBR “facility” at the Columbus Business Technology Center (BTC) and Ohio Supercomputer Center (OSC)
- Run as a self sustaining “service”
- Builds inventory; tissue and associated clinical and analysis data
- Initial focus cancer
OBR – Partners

We couldn’t do this without you:

• The biorepository
  ▪ Omeris – Concept, Management
  ▪ Ohio Supercomputer Center – data warehouse
  ▪ Ohio State University – Consulting, services, training

• Tissue partners – Community hospitals
  ▪ Ohio Health – Riverside Methodist Hospital
  ▪ Others – in discussion

• Academics centers
  ▪ Cleveland Clinic/CASE – Validation
  ▪ OSU – Validation

• Commercial partner
  ▪ Phylogeny
Establishing the OBR

A Phased Approach

• Building Capability: Tissue archive
• Building a Community Hospital Focus: Ohio Health, Riverside Methodist Hospital
OBR locations

- Tissue and pathology block archive storage facility – BTC
- Data warehouse – OSC-Springfield
Building The Ohio BioRepository

Third Frontier funding secured to start building OBR and support Phylogeny

OBR being developed in partnership with OSU & OSC

Leverage partners expertise

Tissue sourcing from OSU (archive) & community hospitals
Tissue Micro-Array Product Line

- Partnership with Phylogeny (Folio) to support TMA production
- Will market own brand and OEM for others
- Phylogeny fixative preserves all mRNA
OBR Tissue Archive

• The problem and the challenge
Pathology Block Archive

- Pathology block archive comprising 144,000 patient records and blocks donated by OSU to the OBR
- 18 year collection from 1950-1967
- Report information annotated into searchable database
- Asset now available to the research community
- 14,214 annotated cancer cases
Pathology Block Archive: Some Numbers

- 83,475 reports examined
- 14,214 annotated entries for cancer
- Cancer cases (malignant and benign) represent 17% of cases
- Cancer (malignant) 13% of cases

<table>
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<th>Anatomic Site</th>
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<td>Urinary bladder</td>
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Data Collection, Access & Security - Archives
Welcome to the Ohio BioRepository (OBR) Website.

The Ohio BioRepository (OBR) initiative comprising a human tissue specimen repository and associated searchable database is lead by Omeris in partnership with OSU, with support from Ohio State University’s Human Tissue Resource Network (HTRN). The repository provides researchers ready access to tissues stored under a variety of preservation techniques ensuring the presence of low abundance mRNAs, and a separate formalin-fixed paraffin block tissue archive. The repository will become a unique asset for fast turnaround on human research studies.

Annotation System
Administration
Preprints of Cancer Reports
Cardiac of breast

HISTORY

Mass right breast 5 months, backache 2 years.

GROSS

A. The specimen submitted for frozen section consists of a large portion of breast measuring 6 x 5 x 3.5 cm. It is covered on one surface by a large ellipse of skin. The skin surface shows slight reddish discoloration and some nodularity. On section through this area a large tumor mass is encountered measuring 3 cm. in diameter. It has a homogeneous gray-pink granular cut surface. It is well demarcated from the surrounding adipose tissue. The specimen from the radical mastectomy consisted of posterior muscle with the overlying subcutaneous tissue and skin. The specimen weighs 960 grams and measures 11.5 x 13 x 6 cm. The covering ellipse of skin measures 10 x 7 cm. In the center of the skin is a previous biopsy incision measuring 7 cm. in length. Beneath the incision is a ragged defect filled with clotted blood. This represents the site of biopsy. There is no gross tumor remaining in this area, the entire apparently having been removed with the biopsy specimen. A single lymph node measuring 9 cm. in diameter is found in the tissues near the axillary portion of the specimen.

B. Submitted separately is a lymph node with surrounding adipose tissue. It is said to represent a lymph node from axillary region.

MICROSCOPIC

Sections made of the tumor mass reveal numerous atypical polygonal epithelial cells lying closely packed into large masses and nests of cells with little intervening stroma except at the periphery of the tumor. The nuclei are dark staining and are round or oval in shape. They vary somewhat in size. Occasional mitotic figures are present. The simple lymph node found shows no evidence of carcinoma and the lymph node submitted separately and labeled as "node from axilla" likewise shows no metastatic tumor.

Diagnosis: Medullary carcinoma of breast.

There is no evidence of metastatic carcinoma in either of the two lymph nodes found.
The Ohio BioRepository (OBR), comprising a human tissue specimen repository and associated searchable database, is led by Omeris in partnership with the Ohio Supercomputer Center (OSC), with support from Ohio State University's Human Tissue Resource Network (HTRN).

The repository provides researchers ready access to tissues stored under a variety of preservation techniques ensuring the presence of low abundance mRNAs, and a separate formalin-fixed paraffin block tissue archive. The repository will become a unique asset for fast turnaround on human research studies.

**About OBR Partners**

**Omeris**, founded in 1986 as the Edison BioTechnology Center, is a non-profit organization designed to build and accelerate bioscience industry, research, and education in Ohio.

**OSC** is Ohio’s answer to high performance computing (HPC) and networking. OSC provides the computational power, infrastructure, and expertise needed to answer the demands of the Ohio education and research community.

**HTRN** unites tissue-based research resources within the OSU Department of Pathology and promotes collaborative research within the OSU Medical Center and related national human research projects.
Public search of annotated PHI free data

You may search the OBR database by any or all of the following values. Fill in the fields using the drop down lists and click "Search".

- OBR ID:
- Age:
- Anatomic Site: any
- Diagnosis:
- Gender: any
- Grade: any
- Malignancy: any
- Procedure Year:
- Race: any
- Tissue Type: any

Advanced Options

Rows to Display Per Page: 20
Order Results By: OBR ID Ascending
Then By: Any Ascending
Then By: Any Ascending

Search | Help | Logout
Pull-down Search Parameters

You may search the OBR database by any or all of the following values. Fill in the fields using the drop down lists and click "Search".

- OBR ID:
- Age:
- Anatomic Site:
  - any
  - Abdomen
  - Adipose Tissue
  - Adrenal Gland
  - Anus
  - Aorta
  - Appendix
  - Artery
  - Atrium
  - Axilla
  - Blood
  - Bone
  - Bone Marrow
  - Brain
  - Brain Stem
  - Breast

- Diagnosis:
  - any
  - Abdomen
  - Adipose Tissue
  - Adrenal Gland
  - Anus
  - Aorta
  - Appendix
  - Artery
  - Atrium
  - Axilla
  - Blood
  - Bone
  - Bone Marrow
  - Brain
  - Brain Stem
  - Breast

- Malignancy:
- Procedure Year:
- Race:
- Tissue Type:

- Advanced Options

- Rows to Display Per Page: 20
- Order Results By:
  - OBR ID
  - Ascending
  - Any
  - Ascending
  - Any
  - Ascending
## Search Output: Breast Cancer Samples

- **814 items found**
- **Page 1 of 41**

### Table

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Hospital Collection
Prospective sample collection from community hospitals

- Tissue sample collection operations at Riverside Methodist Hospital commenced Feb 6th, 2006
- Target is 6,000 samples per year from cancer surgeries
- Snap frozen and formalin QC
- Expand into other OhioHealth hospitals
- Expand into other community hospitals
Steps along the way

• Ohio Health/Riverside MH desire to engage in the research process
• Hospital IRB approval
• Hospital general consenting allows patient to “opt out” of donating remnant tissue for research
• Web-based annotation tool modified
• Hook up to RMH IT systems
Data Collection, Access & Security - RMH
• Web-based data capture tool – manual & automated data push
• Pathology report capture
• Ability to capture additional fields
NCI Leadership Role in Biorepositories

The NCI is leading a national initiative to systematically address and resolve one of the most difficult problems that will drive 21st century cancer research: the limited availability of carefully collected and controlled, high-quality human biospecimens annotated with essential clinical data and properly consented for broad investigational use. This issue has been repeatedly identified by the scientific community as the leading obstacle to progress in cancer research and public health. 

Message From the NCI Director

As we enter the era of molecular medicine, new attention is being focused on biorepositories, collections of human biological materials annotated with demographic and clinical information. 

Highlights:

Job posting: Assistant Director for Biorepositories and Biospecimen Research
See USAjobs.com

First-Generation Guidelines Now Available (more)

Symposium on International Harmonization
NCI Cancer Bulletin (more)
NCI – Office of Biorepositories & Biospecimen Research

- Established 2005
- NCI supported repositories – guidelines
- Clinical biospecimen research
  - Life cycle of biospecimen
    - Medical/Surgical Procedures
    - Acquisition
    - Handling/Processing
    - Storage
    - Distribution
    - Scientific Analysis
    - Restocking Unused Samples
Personalized Medicine
Institute for Personalized Healthcare

- Goal: To make Central Ohio a leader in the emerging field of personalized medicine
- Institute to create warehouse of medical information
- Data would drive clinical decisions toward the “best” therapeutic outcome
- Players: IPHC, OSUMC, Battelle, Siemens AG, OhioHealth, Mt. Carmel Health System, Children’s Hospital, OBR
- OBR to be the IPHC’s biorepository
- Business First – Feb 27, 2006
Acknowledgements

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- **Omeris Board**: Jim Scozzie, Rich Rosen, Peter Kleinhenz
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- **OSU**: Scott Jewell, Laurie Johnson, Jasmine Ramaradjou, Cheryl Reeder
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- **Phylogeny**: Adel Mikhail, Lali Reddy, Sushma Joshi, Patricia Spitzner