Surgery Research Conference

DECEMBER 13, 2017
Research Highlights
“Microbial Dysbiosis and Gene Expression May Explain Disparate Health Outcomes in Ethnic Minorities”

CTSI Traditional Pilot Award application has completed the review process and has been recommended for funding for $50,000 with a project start date of April 1, 2018.
December Publications

General Surgery
Melissa Helm
Kathleen Lak
Rana Higgins
Tammy Kindel
Jon Gould


Mathew Goldblatt
General Surgery
Robotic Skills can be Aided by Laparoscopic Training. Surgical Endoscopy.

Surgical Oncology
Callisia Clarke

Surgical Oncology
Jack Silva
Richard Gorman
Nicholas Berger
Susan Tsai
Kathleen Christians
Callisia Clarke
Harveshp Mogal
Clark T. Gamblin

“The Word on Medicine”

Radio Show on NEWS/TALK 1130 WISN

Transplant Program - December 23, 2017 at 3 pm

Focusing primarily on liver and kidney transplantation

Dr. Johnny Hong, Dr. Stephanie Zanowski, Dr. Ehab Saad, Dr. Mike Zimmerman, Dr. Kathryn Lauer, Dr. Jessa Price, Dr. Sarah Siker, Dr. Shannon Sova and Dr. Tanya Anderson

Colon Cancer and Colonoscopies - January 13, 2018

Focusing primarily on Colon Cancer and screening techniques

Dr. Carrie Peterson, Dr. Tim Ridolfi, Dr. Peter Eichenseer, Dr. William Hall, Dr. James Thomas and Janice Erbe
### Vitality Award
- Full time or full professional effort service to MCW at the rank of Assistant Professor or higher are eligible.
- Intended to promote academic vitality, career development, and clinical and/or research productivity.

### CSAF Grant
- Members in the rank of Assistant and Associate level Professors awarded $20,000, to support surgical scholarship and research and advance the science of surgery.

### RAC New Faculty Pilot Grant
- Due: 3/1/18 - Primary goal of the $25,000 award is to help applicants obtain preliminary results that will enable them to compete successfully for extramural funding.

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## Calendar

### January 2018

<table>
<thead>
<tr>
<th>SUNDAY</th>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
<th>SATURDAY</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>28</td>
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<td>30</td>
<td>31</td>
<td>1</td>
<td>FEBRUARY</td>
<td>2</td>
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<td></td>
<td>MCW Vitality Award Due</td>
<td>MCW Pancreatic Cancer Clinical Symposium Harley Davidson Museum</td>
</tr>
</tbody>
</table>
Next Meeting: January 10, 5-6 pm
Cancer Center Conference Room M

Surgical Oncology Research Update

Susan Tsai, MD, MHS
Amanda Kong, MD, MS
Tracy Wang, MD, MHS
The Division of Research would like to announce:

Priyabrata Mukherjee, Ph.D.
Peggy and Charles Stephenson Endowed Chair, Professor of Pathology,
University of Oklahoma Health Sciences Center,
College of Medicine and Stephenson Cancer Center

"Probing Cellular Processes Using Engineered Nanoparticles"

Thursday, December 14th
1:30 p.m. — 2:30 p.m.
Location: Froedtert West, 1st Floor, Dean Roe Auditorium
How to Get the Most Out of i2b2

Kristen Osinski, MSMI, BBA
Business Analyst, Biomedical Informatics
Clinical & Translational Science Institute

MCW Tissue Bank

Mary Rau
Tissue Bank Manager
Department of Pathology
Regional consortium of Health Care and Academic institutions partnering to advance health through research and discovery
Biomedical Informatics
Clinical Research Data Warehouse

★ Introduction
★ Content
★ Tools
★ Process
★ Access

December 13, 2017
Kristen Osinski, MS
Biomedical Informatics Business Analyst
Biomedical Informatics

Role of Business Analyst

- Facilitate access to CRDW
- Train users (1-on-1 or small team)
  - Provide project-specific training
  - Develop user guide
- Navigate CRDW tools
  - Finding criteria
  - Designing efficient queries
- Translate CRDW source data representation for CTSI research teams and BMI programmers
Content – Source Data

Froedtert & Medical College of Wisconsin

★ Epic Electronic Medical/Health Record
★ GE/IDX Physician Billing System
★ Pre-Epic Systems: Affinity, Intellidose, SIS
★ MCW Tissue Bank Biospecimens Database
★ Social Security Death Master File
★ NAACCR Tumor Registry
★ OnCore Clinical Trials Management System
★ Leukemia (AML/ALL) Registries
Content – Source Data

Children’s & Medical College of Wisconsin

★ Epic (separate EHR from Froedtert)
★ GE/IDX Physician Billing System
★ Future: MCW Tissue Bank Biospecimens

❖ Note
  ▪ All CHW data is separate from Froedtert
  ▪ IDs for common patients are not resolved
## Content – Queriable Facts

The content consists of querable facts from different domains in electronic health records (EHRs). These facts are critical for various analyses and research studies. The data from Froedtert Hospital and Children's Hospital of Wisconsin are included, with Froedtert having more than 1.5 billion records and Children's having more than 142 million records.

<table>
<thead>
<tr>
<th>Concept Domain</th>
<th>Fact Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient/Demographics</strong></td>
<td>Age, Gender, Ethnicity, Race, Death, Zip-3</td>
</tr>
<tr>
<td><strong>Biospecimens</strong></td>
<td>Date, Specimen Type, Tissue Site</td>
</tr>
<tr>
<td><strong>Clinical Registries</strong></td>
<td>Critical Care, Manometry, Leukemia</td>
</tr>
<tr>
<td><strong>Clinical Trials</strong></td>
<td>Enrolled in OnCore CTMS: Yes/No</td>
</tr>
<tr>
<td><strong>Diagnoses</strong></td>
<td>ICD-9, ICD-10</td>
</tr>
<tr>
<td><strong>Encounters</strong></td>
<td>Type, Department, Specialty, Observations</td>
</tr>
<tr>
<td><strong>Lab Results</strong></td>
<td>LOINC-based Laboratory, PFT &amp; CVT results</td>
</tr>
<tr>
<td><strong>Medications Ordered</strong></td>
<td>Mod: Inpt mode, Outpt mode, Abstracted hx</td>
</tr>
<tr>
<td><strong>Medications Admin’ed</strong></td>
<td>Mod: Pharm Class, MAR Action, Route, Dose</td>
</tr>
<tr>
<td><strong>Procedures</strong></td>
<td>Mod: data source [e.g. Order, Encounter, Billing]</td>
</tr>
</tbody>
</table>
# Content – Data Integration

**MCW Tissue Bank** fact count > 115K

<table>
<thead>
<tr>
<th>Concept Name</th>
<th>Fact Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acquisition Date</strong></td>
<td>Month &amp; Year; 2013 thru 2016</td>
</tr>
<tr>
<td><strong>Pathology Status</strong></td>
<td>Benign, Diseased, Malignant, Normal, Tumor</td>
</tr>
<tr>
<td><strong>Specimen Type</strong></td>
<td>Buffy Coat, DNA, Frozen Tissue, Plasma</td>
</tr>
<tr>
<td><strong>Tissue Site</strong></td>
<td>Blood, Bone Marrow, Breast, Skin, Soft Tissue</td>
</tr>
<tr>
<td><strong>Protocol (future)</strong></td>
<td>Tissue, Cord Blood</td>
</tr>
</tbody>
</table>
## Content – Data Transformation

<table>
<thead>
<tr>
<th>Clinical Use Context</th>
<th>Research Use Context</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual patient</td>
<td>Aggregated patient cohorts</td>
</tr>
<tr>
<td>Real-time access (supports workflow)</td>
<td>Delayed access (supports 2ndary use)</td>
</tr>
<tr>
<td>Implicit (patient chart is pre-programmed to enable rapid human inference)</td>
<td>Explicit (total re-assembly of data w/date-tagging, standardization and coding)</td>
</tr>
<tr>
<td>Identified</td>
<td>De-identified and/or Identified</td>
</tr>
<tr>
<td>Treatment, Payment, Operations</td>
<td>Clinical &amp; Translational Research / Quality Improvement (ops research)</td>
</tr>
</tbody>
</table>
Tools – Use Cases

- **Query**
  - ✓ Hypothesis Feasibility/Development
  - ✓ Cohort Counts for grant submission
  - ✓ Cohort Definition for data analysis

- **Data Extraction**
  - ✓ De-identified retrospective analysis
  - ✓ Identified prospective data collection
  - ✓ Identified prospective recruitment
Tools – Use Context

- **Query** – De-identified, unlimited use
  - ✓ i2b2
  - ✓ TriNetX

- **Data Extraction**
  - ✓ Honest Broker
    - ▪ De-identified – unlimited use, no IRB req
    - ▪ Identified – requires IRB approval

❖ Separate tools for F&MCW vs. Children’s
Tools – i2b2
informatics for integrating biology & the bedside

✓ Self-service
✓ Concept Tree
✓ Cohort Discovery
➢ Generates Cohorts
  • Distinct Patient Counts
  • Saves Patient Sets
➢ Analyzes Patient Sets
  • Demographic Snapshots
  • Criteria Timelines
Tools – i2b2

Search for Concepts by Names (terms) or Codes
Tools – TriNetX Query

- Pharma funded
- Uses same fact base as i2b2
  + Demographics
  + Diagnoses
  + Procedures
  + Medications
  + Labs
  + Cohort Analysis
- No site facts, yet...

Networks
- Medical College of Wisconsin CHW Network
- Medical College of Wisconsin Froedtert Network
- Medical College of Wisconsin Joint Network

Demographics
- Demographics

Patients
- 1,133,650
Tools – Honest Broker Data Extraction

Query Tool Integration
- i2b2 – Programmed link
- TriNetX – Manual link

Self-Service Data Extraction
- De-identified (cohorts > 10)
- Identified (no minimum)
  ✓ Approved IRB protocol
Honest Broker Data Tables

- **Standard tables**
  - MRN common to all tables
  - Define output date parameters
  - .CSV output format
  - Post hoc sorting/filtering required
  - Link tables data by MRN or Encounter ID

- **Custom tables**
  - Built per customer request
  - BMI service center ($100/hour)
  - Ex: Notes content, flowsheet data
Process – Overview

1. Complete a Data Release Agreement for each project
   a) Each project must have a faculty PI
   b) External (non-CTSI) collaborators must sign a Data Sharing Agreement

2. Define and save a cohort using a Query Tool
   a) Build Research vs. Control cohorts
   b) Stratify cohorts using base queries

3. Extract data using Honest Broker (HB) Tools
   a) i2b2 query – automatic query link (most common)
   b) TriNetX query – exported patient list
   c) MCW Tissue Bank barcode list
   d) Identified MRN patient list (default)
Process – HB automatic link

- Click on Select Patients
- i2b2 queries are available for selection
- Select Tables - build your data shopping cart

- Click Run Extract
- Honest Broker sends email when extract is ready
- Download and open data table(s) in Excel (.csv)
Process – HB manual patient set

Select Patients

Build a patient cohort from MRN, Barcode or TriNetX
Manually build a patient cohort using a list of Froedtert MRN codes in 00000000 format (must include leading zeros), MCW Tissue Bank barcodes, or TriNetX patient IDs

Please Designate A Cohort Name *

☐ Check if the numbers are barcodes
☐ Check if the numbers are from TriNetX

Please use comma, space, or new line between the numbers. (Max number: 9,999)

Input the Numbers *
Access

1. Join the CTSI

2. Have current CITI training in Human Subjects Research
   a) Make sure MCW is your primary institution on CITI website
   b) Complete all MCW-required CITI training modules

3. Complete a CRDW Data Release Agreement
   a) PI must be MCW faculty or have adjunct faculty appointment
   b) All team members must have MCW domain (@mcw.edu) account to access tools

★ Collaboration with CTSI partner institutions is encouraged!
Questions?
MCW TISSUE BANK

Introduction to the MCW Tissue Bank
MCW Tissue Bank: Mission

The MCW Tissue Bank's mission is to centralize collection of discard tissue, blood, and associated clinical information for intended future use in research by MCW faculty. The bank will also provide support services for MCW investigators with studies involving human specimens.
MCW Tissue Bank: Who We Are

Saul Suster, MD
MCW Tissue Bank Director

Mary Rau
MCW Tissue Bank Manager

Lauren Parsons, MD
QC Pathologist

Janelle Lang-Piette
Research Technologist I

Ellen Schneider
Research Technologist II

Mollie Patton
Pathologists’ Assistant

Mónica Thom
Asst. Pathologists’ Assistant

Allia Nelson
Research Coordinator

Jason Kirkpatrick
Research Coordinator

Lauren Parsons, MD
QC Pathologist

Ellen Schneider
Research Technologist II

Mollie Patton
Pathologists’ Assistant

Mónica Thom
Asst. Pathologists’ Assistant

Allia Nelson
Research Coordinator

Jason Kirkpatrick
Research Coordinator
MCW Tissue Bank: Consent

- 2 consent forms:
  - *General bank consent covers:*
    - Banking discard tissue from all future procedures
    - Banking a one-time blood sample collected at the same time as a clinical draw
    - Linking any banked sample to clinical data
    - Patients are only approached once
  
  - *Maternal Placenta Cord Blood banking consent covers:*
    - Banking placenta and discard tissue from specified birth
    - Banking a one-time blood sample collected at the same time as a clinical draw
    - Banking cord blood from specified birth
    - Linking any banked sample to clinical data
    - One consent per pregnancy
MCW Tissue Bank: Consent Cont’d

- IRB approved training program for staff to become consenter for the MCW Tissue Bank
  - Open to all healthcare professionals (MAs, RNs, PACs, NPs, MDs etc.) and study staff
  - Approximately one hour to complete training
  - Staff elicits informed consent from subjects

- Approved areas of operation
  - Consenting can be introduced into any area of Froedtert hospital, clinics, & affiliated hospitals & clinics
  - Currently active in the Cancer Center, Maternal Fetal Medicine, Pulmonary Clinic, Vascular Clinic, & various Froedtert Hospital locations, St. Joseph’s Kramer Cancer Center, Begin Community Memorial Hospital Cancer Center Monday 12/11/17

- Tissue Bank staff handles order processing/documentation
MCW Tissue Bank: General Bank Specimens

- One-time blood sample is collected during clinical draw.
- Tissue removed during surgical procedures are sent from OR to pathology for clinical diagnosis.
- Specimens sent from consented participants are flagged with a blue label by OR staff.
- Labelled specimens are reviewed by Bank’s Pathologists’ Assistant to determine what is needed for diagnosis and what can be banked, if anything.
- If banking can occur, the banking protocol is followed.
MCW Tissue Bank: Banking Protocol

**Tumor or Diseased Tissue**
- First piece: Snap frozen in LN₂
- Second piece: Fixed in formalin
  - Frozen section H&E slide
  - FFPE block and H&E slide

*Pieces 3-10, if available, will be snap frozen and one H&E slide created from each

**Normal Tissue**
- First piece: Snap frozen in LN₂
- Second piece: Fixed in formalin
  - FFPE block and H&E slide

*Pieces 3-10, if available, will be snap frozen
MCW Tissue Bank: Maternal Research
Placenta and Cord Blood Bank Specimens

- Specimens are for research use only
- All specimens processed during normal business hours
  - Monday-Friday, 8:00 AM-5:00 PM
- Sections of the placental disc, umbilical cord, and placental membranes are:
  - Snap frozen
  - Fixed in formalin for a block and a slide
- Cord blood is collected
- Maternal peripheral blood is collected during pregnancy
# MCW Tissue Bank: Services Offered to Independent Studies

<table>
<thead>
<tr>
<th>Tissue Bank Services</th>
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<tbody>
<tr>
<td>Tissue procurement &amp; processing</td>
<td>Whole blood processing</td>
</tr>
<tr>
<td>Sample handing, storage, &amp; administration</td>
<td>DNA &amp; RNA Isolation</td>
</tr>
<tr>
<td>Nucleic acid quality/quantity analysis</td>
<td>Letters of support</td>
</tr>
<tr>
<td>Bone marrow processing</td>
<td>FFPE processing &amp; embedding</td>
</tr>
<tr>
<td>Other Services Available Per Request</td>
<td></td>
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</tbody>
</table>
MCW Tissue Bank: Limitations

- Eligible patients
- Principal Investigator (PI)
- Safeguard clinical care
  - Must leave diagnostic/staging tissue intact
- Pre-treatment of tumors
  - Necrosis/viability, fibrosis, size
- Hours of operation
  - Monday-Friday, 8:00 AM-5:00 PM
- Specimen transport
- Order limitations
MCW Tissue Bank: Distribution Process

- Specimen inquiry
  - Self-service query through i2b2
    - Required for further filtering of specimens by medications, treatment, etc.
    - Requires CITI training
    - Results are de-identified

- Specimen and/or service request through online form
- Quote for request sent to PI
- Requests go to governing committees for approval
  - IRB approved protocol required for HIPAA identifiers
- PI and Bank staff work on distribution
MCW Tissue Bank: Distribution Process

**Specimen/Service Inquiry**

**Online Request Form**

**Quote for Services Provided**

**Tissue Bank’s Utilization Committee**

**Bank Staff**

**Decision Communicated to PI**

**Bank Staff**

**Bank Staff**

**PI**

**PI**

**Bank Staff**

**PI**

**PI**

**PI**

**PI**

**Tissue Bank’s Executive Committee**

**Does PI Need HIPAA Identifiers?**

**IRB Approved Protocol Required**

**Distribution Process**

**Yes**

**No**
MCW Tissue Bank: Summary

- MCW Tissue Bank is a shared research resource available to MCW investigators
- Affordable specimens and services
- MCW Tissue Bank staff will work with investigators
  - We continually adapt to investigators’ needs

MCW Tissue Bank Contact Information
Main phone: 414-805-8829
This line is open for staff and patients interested in contacting the Bank
Monday-Friday, 8:00 AM-5:00 PM

Tissue Bank Manager: Mary Rau
Phone: 414-805-9569
Email: mrau@mcw.edu
Next Meeting: January 10, 5-6 pm
Cancer Center Conference Room M

Surgical Oncology

Susan Tsai, MD, MHS
Amanda Kong, MD, MS
Tracy Wang, MD, MHS