Translational Research Enhancement Core
(Patient Registry, Clinical Information Systems, and Tissue Repository)
Jim Potter – Core PI/PD

Hopkins Conte Digestive Diseases Basic and Translational Research Core Center
Mark Donowitz, MD – Center PI

The Division of Gastroenterology and Hepatology
The Johns Hopkins University School of Medicine
It is impossible to thank everyone who has contributed to the development and testing of informatics for clinical research. I have highlighted only a few in the following slide, but we would not be successful without the efforts and contributions of many others. I am in awe at the dedication of effort and intellect by so many to enable clinical research.
Translational Research Enhancement Core

**SOM Informatics Support**

Dr Dan Ford - The Vice Dean for Clinical Research  
Diana Gumas - IT Director, SOM Welch Health Sci Informatics  
Joseph DiMaggio - IT Project Manager caTissue/CRMS  
Dorothy Damron - Dir Clinical Research Admin CRMS  
Chris Shafer - Dir of Center for Clinical Data Analysis  
Dave Thiemann - CCDA  
Sam Meiselman – SQL DBA, CCDA  
Matthew Marcetich – TREC caTissue superuser

- **CISSCI Committee** (Committee on Information Systems to Support Clinical Investigation )
- **Research Data Sub Council** (Stuart Ray, Jennifer Kulynych; to enable high quality, innovative data research, while establishing a uniform process and standards to protect security and privacy)
- **Biospecimen Committee**
- **CRMS SOM Development Committee:**
  - JHMCIS, Integration Team – Medical Informatics  
  - Center for Clinical Data Analysis - I2b2/SHRINE Pilot Group
Change Management

Anticipate and Embrace Change

“The only change people don’t fear is the change that jingles in their pockets”
Informatics in Service of Clinical Research

Ask “WHAT”, and then “HOW”

“Vision Drives Change”
“To wrest from nature the secrets which have perplexed philosophers in all ages, to track to their sources the causes of disease, to correlate the vast stores of knowledge, that they are quickly available for the prevention and cure of disease – these are our ambitions.”

- Sir William Osler, 1906
Hopkins NIH/NIDDK Conte Digestive Diseases
Basic & Translational Research Core Center

Mission
The goal of this Center is to advance basic and translational GI research at Hopkins and to encourage further interactions among the members of our research base.

Mark Donowitz, MD
Director

Ann Hubbard, PhD
Steve Leach, MD, PhD
Associate Director
Associate Director

Bob Cole, PhD
Director
Proteomics Core

Olga Kovbasnjuk, PhD
Ann Hubbard, PhD
Associate Directors
Imaging Core

Jim Potter
Director
Translational Research Enhancement Core

Nick Zachos, PhD
Director
Mouse Physiology Core
The Hopkins Digestive Diseases Basic and Translational Research Core Center is a NIDDK Silvio Conte Core Center which has as its goal to advance basic science and translational digestive diseases research at the Johns Hopkins University School of Medicine.

The major areas being studied include:

1. Epithelial Transporter Function and Regulation, including trafficking, protein-protein interactions and bioinformatics.

2. Inflammation, fibrosis and cancer development, including infectious diarrheal diseases, inflammatory bowel diseases, fatty liver, alcoholic and non-alcoholic steatohepatitis, obesity, and pancreatitis.

3. Neurogastroenterology


5. Epigenetic Aspects of GI Cancer.
Cores

Mouse Physiology Core
The goal of the Mouse Physiology Core is to advance the understanding of digestive diseases by providing services to increase the ease and efficiency of studying the physiology and pathophysiology of mouse models, including those knockout and transgenic models in which colitis and small intestinal disease occur.

Imaging Core
The goal of the Fluorescence Imaging Core is to provide state-of-art light microscopy technology to the members of the Hopkins Basic Research Digestive Disease Development Center and to the whole Hopkins scientific community.

Proteomics Core
The Proteomics Core uses mass spectrometry coupled to one (1D) and two (2D) dimensional separations by column chromatography or gel electrophoresis to identify, quantify or characterize proteins and their post-translational modifications, that are expressed in well characterized protein fractions from the small intestine, colon, kidney, liver and pancreas.

Translational Research Enhancement Core
The overarching goal of the Translational Research Enhancement Core (TREC) is to provide the expertise and infrastructure for cost effective tissue and clinical data collection that meets Best Practices through the establishment of uniform Standard Operating Procedures (SOPs) to promote scientific advances by, and scientific interactions among Core users, collaborative investigators and young investigators, without each investigator having to invest in the equipment/resources or to individually work out the specific SOPs.
Translational Research Enhancement Core (TREC)

Goal of the TREC:

- To provide a strong scientific foundation for clinical and translational research
- To promote scientific advances by, and scientific interactions among Core users, collaborative investigators and young investigators.
- To provide the expertise and infrastructure for cost effective tissue and clinical data collection
- To follow Best Practices through the establishment of uniform Standard Operating Procedures (SOPs)
Advantages of the TREC

- Harvest of Biospecimens with associated clinical data thus allowing specialized study of disease processes
- Data Security and Integrity
- Facilitate Hypothesis Driven Research
- Facilitate cohort identification, IRB approval, Patient Screening / Registration / Consent
- Best Practices/SOP
Specimen Collection:
Factors to be considered:

- Purpose of the Biorepository
- Best Practices / SOPs
  - The Scientific Foundation for the Research
- Consent
- Governance / Oversight
- Funding Support
- Hardware
- Software/Audit/Security
- Enterprise Bioinformatics Systems
- Personnel (FTE)
Translational Research Enhancement Core
GI Division Sponsored Units

Clinical Research

Basic Research

Translational Research

Clinical Research Unit
Registry/Database
CRMS DB

Tissue Bank
Repository
CaTissue DB
Translational Research Enhancement Core

Provides infrastructure for specimen (GI-TxB) and clinical data collection (CRU) following established Best Practices and Standard Operating Procedures as defined by an Oversight Committee

CRU Roles:
- patient identification
- patient recruitment
- facilitation of patient trials
- patient registry / cohort discovery

Tissue Bank Roles:
- Collection and transport
- Annotation and DB entry
- Processing
- Storage
- Management
- Quality assurance
- Distribution (shipment)
- Ethical use
- Oversight
Governance - TREC Oversight Committee

Division Director
Anthony Kalloo

TREC Board
TREC PI/PD-Jim Potter, Center PI – Mark Donowitz,

Investigators
- One PI from each of “8 study sections”
- At least two rotating independent non-GI, JHU investigators

External Scientific Advisory Committee
Governance/Oversight - Roles

• Provide ethical oversight of all research involving repository specimens
• Assure the best possible biospecimen quality
  ✓ BP are followed
  ✓ SOP Manual reviewed, updated and followed
  ✓ External Scientific Review
Governance/Oversight - Roles

• Provide consistent documentation
• Establish guidelines for collection, processing, storage and retrieval of specimens
• Assessment of new technologies and the incorporation of new technologies into the repository
• Assure the fair and impartial utilization of specimen resources
Translational Research Enhancement Core

Highlights – First Year

- 21,000 specimens by 7-30-12
- Completed implementation of Enterprise Data Systems
- Organoid Sample Bank
- 4 significant grant proposals by young investigators including R21 and ADA
- Collaborations
- Directed collections for pancreas, liver and lumen
- $2 Million in additional support
- 20 publications in first year
Translational Research Enhancement Core
Enterprise Systems

What is in Place?

- CRMS
- EPR 2020 (Amalga) –i2b2 Pilot /SHRINE,
  -Center for Clinical Data Analysis
- EPIC
  ✓ Clinical Research Team
  ✓ Consents
- Surgical Path
- Clinical Registries Workshop
- CaTissue
  ✓ Consultant-Trainer
  ✓ Coordinator-Programmer
Clinical Research Management System

Translational Research Enhancement Core
Enterprise Systems

Clinical Registry Development

Consents

Surgical Path

Epic (EPR2020)
I2b2 - pilot
ICTR CCDA

caTissue – Tissue Repository Software
(Support for multiple repositories within a single caTissue instance)
(Clinical Annotation with Specimens)
caTissue Suite:

- **Core Functions / Modules**
  - **Administration**: Create and edit users, protocols, and storage systems associated with a biospecimen inventory. Manage multiple repositories under one roof.
  - **Biospecimen**: Create and edit data concerning participants and their corresponding biospecimens.
  - **Query**: Identify biospecimens and their data based upon one or more selection criteria.
Key Functions and Benefits of caTissue Suite

• **Search**
  Allows biospecimen resource staff and scientists alike to search for biospecimens based on a combination of properties

• **Biospecimen Tracking**
  Allows biospecimen resource staff to record events related to biospecimen processing and quality assurance and to annotate biospecimens with pathological, clinical, and custom data

• **Biospecimen Inventory Management**
  Allows biospecimen resource staff to record data about biospecimen collection, storage, requests, and distribution.
Most Biospecimen Research

- Focus on Analysis not collection or processing
Today’s Research & Path Non-CLIA Lab

- No Standardized SOP’s for collection, processing - few SOP’s for storage & analysis of biospecimens

Collection (variables not validated)

Processing (variables not validated) → Storage → Analysis = Improve Pt. Outcomes
caTissue - Benefits

For University

- Centralized application
- HIPAA compliance easy to monitor
- Data Security and Integrity
- Multiple Repositories within one caTissue instance

For PIs:

- No need for custom databases
- Easier data sharing
- Improved data organization
- Study Team can enter participants
- Powerful Query Capability
caTissue - Needs

- Ongoing Development of the Existing System
  - Krishagni offshore support
  - Users Group
- Integration with CRMS and Other Systems
TREC Informatics Needs

1. An enterprise informatics solution for multicenter consortiums - The BETRNet Virtual Biorepository DB

BETRNet – Barrett’s Esophagus Translational Research Network

- U Penn
- Case Western
- UNC
- Columbia
- Michigan
- U of Washington
- Wash U
- Hopkins
- NCI
- Mayo Clinic
- NIH
- Fred Hutchinson CRC

2. Clinical Registry Development Capabilities / Cohort Discovery

3. Link to external datasets
   - BETRNet Biorepository Database
   - CAPS Study (Ca Pancreatic Screening) (Multinational)

4. Tiered Consents, Consents linked to specimens
TREC and Gastroenterology Solutions

1. An enterprise informatics solution for multicenter consortia-
The BETRNet Virtual Biorepository DB

cdTissue

2. Clinical Registry Development Capabilities / Cohort Discovery

i2b2 (Informatics from the Bench to the Bedside)

3. Link to external datasets (BETRNet Biorepository Database, CAPS Study)

I2b2 SHRINE (Shared Health Research Information Network)

4. Tiered Consents, Consents linked to specimens

EPIC - CRMS
# Hopkins Conte Digestive Diseases Basic and Translational Research Core Center

## Barrett's Cryo-Preserved Specimens by Pathology Diagnosis and Event

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<th></th>
<th>Normal</th>
<th>Barrett's-No Dysplasia</th>
<th>Barrett's-Indeterminate</th>
<th>Barrett's Low Grade Dysplasia</th>
<th>Barrett's High Grade Dysplasia</th>
<th>Barrett's AdenoCA</th>
<th>Barrett's Squamous-CA</th>
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## 1.0ml Serum Aliquots of Barrett's Patients by Visit Diagnosis and Event

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<th>Barrett's-No Dysplasia</th>
<th>Barrett's-Indeterminate</th>
<th>Barrett's Low Grade Dysplasia</th>
<th>Barrett's High Grade Dysplasia</th>
<th>Barrett's AdenoCA</th>
<th>Barrett's Squamous-CA</th>
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<td>Barrett's No Dysplasia</td>
<td>Barrett's Low Grade Dysplasia</td>
<td>Barrett's High Grade Dysplasia</td>
<td>Barrett's AdenoCA</td>
<td>Total Barrett's Specimens</td>
<td>Non-Barrett's, Non AdenoCA Control</td>
<td>Total Specimens</td>
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<td>850</td>
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## I2b2 Query of EPR 2020

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<th>BE-LGD</th>
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*Sam Meiselman, CCDA*
# I2b2 Query of EPR 2020

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</table>

Sam Meiselman, CCDA
<table>
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<tr>
<th>Patients</th>
<th>Mutation 1st allele</th>
<th>Mutation 2nd allele</th>
<th>Age of onset</th>
<th>Ceruoplasmin mg/dL</th>
<th>Cu Serum ug/dL</th>
<th>Cu Urine ug/24 hr</th>
<th>KF ring (%)</th>
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<td>H1069Q</td>
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<td>61.2 [34]</td>
<td>163 [255]</td>
<td>+ (28%)</td>
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<td>S653Y</td>
<td>-</td>
<td>9.2</td>
<td>35</td>
<td>135</td>
<td>-</td>
</tr>
<tr>
<td>G</td>
<td>H1069Q</td>
<td>S653Y</td>
<td>22</td>
<td>nd</td>
<td>22</td>
<td>30</td>
<td>-</td>
</tr>
<tr>
<td>J</td>
<td>H1069Q</td>
<td>S653Y</td>
<td>21</td>
<td>3.5</td>
<td>27</td>
<td>1050</td>
<td>+</td>
</tr>
<tr>
<td>BP</td>
<td>H1069Q</td>
<td>S653Y</td>
<td>29</td>
<td>46.4</td>
<td>131</td>
<td>162</td>
<td>+</td>
</tr>
<tr>
<td>BP prior to LT</td>
<td>H1069Q</td>
<td>S653Y</td>
<td>32</td>
<td>14</td>
<td>250</td>
<td>3335</td>
<td>+</td>
</tr>
</tbody>
</table>
TREC and Gastroenterology Needs

3. Clinical Registry Development Capabilities / Cohort Discovery

--Self Service

The Division of Gastroenterology is pursuing clinical registries in all subspecialties of GI, beginning with already funded initiatives, including pharmacological testing with organoids, lineage/family studies with FAP and IBD, GWAS in IBD, HCC, Cholangio Ca, Pancreatic Ca, diarrheal dis., Gi Motility, Gastric Neuroendocrine disorders, and liver disease.

There is a great need to share data.
Scenario: Combined Demographics, Diagnosis and Time Constrained Lab Results Query
## JH i2b2 Pilot – Phase II

<table>
<thead>
<tr>
<th>Summary Task</th>
<th>Status</th>
<th>Data Set Size</th>
<th>Estimated Completion</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Mapping and Dimension</td>
<td>Done</td>
<td>2.5 Million</td>
<td>11/23/2012</td>
<td>Patients and visits based on EPR2020 identity backbone including multi-institution and multi-mrn references</td>
</tr>
<tr>
<td>Visit Mapping and Dimension</td>
<td>Done</td>
<td>42 Million</td>
<td>11/23/2012</td>
<td></td>
</tr>
<tr>
<td>Provider Dimension</td>
<td>Done</td>
<td>35073</td>
<td>11/26/2012</td>
<td>contents of EPR/EPR2020 Provider dictionary (CDTProvider)</td>
</tr>
<tr>
<td>Demographics</td>
<td>Done</td>
<td>2.5 million</td>
<td>11/30/2012</td>
<td>Demographics to include: Age (i2b2 shifts age in older patients where patient could be identified), Zipcode, race, gender</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>In Progress</td>
<td></td>
<td>12/6/2012</td>
<td>Diagnosis based on ICD9 codes from IDX via EPR2020.</td>
</tr>
<tr>
<td>Procedures</td>
<td>In Progress</td>
<td></td>
<td>12/6/2012</td>
<td>Procedures based on CPT and ICD9 coded from IDX via EPR2020.</td>
</tr>
<tr>
<td>Lab Data</td>
<td>Not Started</td>
<td></td>
<td></td>
<td>Finalized Lab result data from PDS via EPR2020, Phase II will load PDS existing ontology as is defined in EPR2020</td>
</tr>
<tr>
<td>Med Data</td>
<td>Not Started</td>
<td></td>
<td></td>
<td>Dispensed Meds from SCM, Phase II will use rxNorm mapping where possible, otherwise Multim ontology as is in SCM.</td>
</tr>
</tbody>
</table>

Chris Shafer, CCDA
### Sample Registry Query

<table>
<thead>
<tr>
<th>Category</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic</td>
<td>• Adults Aged 21-64</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>• Type 2 Diabetes Mellitus</td>
</tr>
<tr>
<td></td>
<td>• Obesity</td>
</tr>
<tr>
<td>Lab Results</td>
<td>• HbA1c $\leq$ 8.5% within 8 months</td>
</tr>
</tbody>
</table>

Chris Shafer, CCDA

Query of Dr Jeanne Clark
I2b2 at JHMI

The Find Patients Query Engine
Diagnosis Selection 1 of 2

[Diagram showing a query tool for selecting diagnoses, with an emphasis on diabetes mellitus, type II.]
Diagnosis Selection 2 of 2
Lab Result Selection

i2b2 Query & Analysis Tool

Navigate Terms
- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
- Expression Profiles Data
- Laboratory Tests
  - Chemistry
    - Anemia Related Studies
    - Blood Gases
    - Blood Gases/Oximetry
    - Cardiac Tests
    - CSF Chemistries
    - Endocrine Studies
    - Fetal Lung Maturity
    - Fluid Chemistries
    - General Chemistries
    - Hemoglobin
      - GHBA1C (Group:GHBA1C)
        - HEMOGLOBIN A1C, WB (LOINC:17856-6)
        - HGB A1C (LOINC:4548-4)
        - Z-GLYCOHEMOGLOBIN (LOINC:4549-2)
    - Lipid Tests
    - Liver Function Tests
    - Lytes/Renal/Glucose
    - Thyroid Studies
    - Urine Chemicals Random
    - Urine Chemicals Timed
- Clinical Pharmacology
- Concomitant Drugs
- Dosage Form
- Dependent_vars

Query Tool
- Query Name:
- Temporal Constraint: Treat all groups independently

Group 1
- Dates: 18-34 years old
- Occurs > 0x
- Exclude: Treat independently
- one or more of these
- AND

Group 2
- Dates: Diabetes mellitus, type II
- Occurs > 0x
- Exclude: Treat independently
- one or more of these
- AND

Group 3
- Dates: HGB A1C (LOINC:4548-4)
- Occurs > 0x
- Exclude: Treat independently
- one or more of these
- AND

Run Query
Clear
Print Query
3 Groups

Query Status

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Lab Result Date Range

Chris Shafer, CCDA
Running and Naming a Query

Chris Shafer, CCDA
Printing a Query

Query Name: Diabetes Type2, Obesity, with HbA1c <= 8.5%
Temporal Constraint: Treat all groups independently

Group 1

Date From: none Date To: none Excluded? false Occurs X times: > 0 Relevance %: 100 Temporal Constraint: Treat Independently

Path | Concept/Term | Other Information
--- | --- | ---
Demographics \ Age \ 18-34 years old | 18-34 years old | 
Demographics \ Age \ 35-44 years old | 35-44 years old | 
Demographics \ Age \ 45-54 years old | 45-54 years old | 
Demographics \ Age \ 55-64 years old | 55-64 years old | 

Group 2

Date From: none Date To: none Excluded? false Occurs X times: > 0 Relevance %: 100 Temporal Constraint: Treat Independently

Path | Concept/Term | Other Information
--- | --- | ---
Diagnoses \ Diabetes mellitus, type II [non-insulin dependent (~)] or unspecified type with hyperosmolarity, not stated as uncontrolled | Diabetes mellitus, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type with hyperosmolarity, not stated as uncontrolled | 
Diagnoses \ Metabolic and immunity disorders \ Obesity and other hyperalimentation \ Obesity | Obesity | 

Group 3

Date From: 04/01/2012 Date To: 12/31/2012 Excluded? false Occurs X times: > 0 Relevance %: 100 Temporal Constraint: Treat Independently

Path | Concept/Term | Other Information
--- | --- | ---
Labtests \ Chemistry \ Hgb A1C (Group:GHB1C) \ Hgb A1c (LOINC:4548-4) | HGB A1C (LOINC:4548-4) | LE : 8.5 %

Finished Query: "Diabetes Type2, Obesity, with HbA1c <= 8.5%"
Compute Time: 18 secs
Patient Set for "Diabetes Type2, Obesity, with HbA1c <= 8.5%"
Number of patients for "Diabetes Type2, Obesity, with HbA1c <= 8.5%"
patient_count: 189
Saving a Query

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Quality (ICD9 Codes)

Fast is fine, but accuracy is everything.

(Wyatt Earp)

Caution – Data Validity Must Be Monitored
Future State

- Single platform – Epic
- Enterprise Governance
- Research Architecture
- Center for Clinical Data Analysis
- Self – Service
- Open Source Tools
- Questions
I2b2 Demo – JH Instance

- Clinical Analytics Team and CCDA
- Positioning for Enterprise Launch
  - SQL and Linux Servers from ESM/Midrange/Cloud Services
  - Pending integration with Enterprise Active Directory
  - Data sources to include EPR2020 and SCM
- Project Phases
  - Demo Phase
  - Starting Data Set Phase (EPR2020)
  - Cross System phase (Blended EPR2020 / SCM)
  - Full Data Set Phase
Use Case: Search Q of patients with Fragile X diagnosis in Maryland. Output is sample cohort for IRB request to contact patients with diagnosis for invitation to participate in JHM study

Chris Shafer, CCDA
Example of Data Accessible Through i2b2/SHRINE

BETRNet Virtual Biorepository Database
Overall structure/workflow

Table 1
Patient
(Demographics/Baseline)

Table 2
Esophageal disease history

Table 3
Exposure history

Table 4.1
Endoscopy

Table 4.2
Blood draw

Table 4.3
Cytosponge

Table 4.4
Esophagectomy

Table 5.1
Tissue
(Endoscopy, esophagectomy)

Table 5.2
Blood
(Blood draw)

Table 5.3
Cytology
(Endoscopy, Cytosponge)

Table 6
Outcomes

Add a procedure for this case

Add a specimen for this procedure

Cross-sectional
Longitudinal
Table 1
Demographics/baseline
Repeated measures: No
Child of: N/A

<table>
<thead>
<tr>
<th>(skip logic)</th>
<th>#</th>
<th>Variable name</th>
<th>GUI format</th>
<th>Permissible values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics / baseline</td>
<td>01</td>
<td>Patient ID</td>
<td>Comment box</td>
<td>Character string</td>
</tr>
<tr>
<td>Demographics / baseline</td>
<td></td>
<td>Consent status</td>
<td>Dropdown menu</td>
<td>Agree, Disagree, Withdraw consent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a) Date of consent</td>
<td>Calendar</td>
<td>YYYY-MM-DD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Type of consent</td>
<td>Checkboxes</td>
<td>Primary research, Secondary research, Broad research, Associated with medical information, Re-contact patient</td>
</tr>
<tr>
<td>Demographics / baseline</td>
<td>03</td>
<td>Date of baseline data collection</td>
<td>Calendar</td>
<td>YYYY-MM-DD</td>
</tr>
</tbody>
</table>

One-time measures

- Database case ID assigned upon case submission. All measures for a given case are keyed to this ID. Research sites are responsible for maintaining a concordance log to match database case ID to local study ID, medical record number, or other unique local identifier.
- Patient consent for participation in biomarker research. Data accepted only for cases with consent status indicated as 'Agree'.
- Date on which consent form is signed by patient.
- For patients who agree to participate in research, record type of consent.
  - Primary: Patient consents to use of specimen/data only in the study specifically defined and described in the consent document.
  - Secondary: Patient consents to use of specimen/data in additional studies beyond the scope of the specific study defined in the consent document.
  - Broad: Patient consents to use of specimen/data in any biomedical study.
  - Associated with medical information: Patient consents to association of specimen/data with medical record and history.
  - Re-contact patient: Patient consents to future contact about potential use of specimen/data in future studies.

All categories that apply should be indicated.

For patients enrolled in BETRNet studies, the term 'research consent', allowing specimens to be labeled 'associated with medical information' will be used to maximize accessibility of specimens and data across the network.
Table 3

Exposure history
Repeated measures: No
Child of: Demographics/baseline

<table>
<thead>
<tr>
<th>Table (skip logic)</th>
<th>#</th>
<th>Variable name</th>
<th>GUI format</th>
<th>Permissible values</th>
<th>Definition, disambiguation, or other data collection note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure history</td>
<td>01</td>
<td>What is the patient's smoking history?</td>
<td>Dropdown menu</td>
<td>Ever-smoker, Never-smoker, Unknown</td>
<td>Patient history of smoking tobacco products. Ever-smoker ( \rightarrow ) Patient has smoked at least 100 cigarettes in his or her lifetime, Never-smoker ( \rightarrow ) Patient has smoked fewer than 100 cigarettes in his or her lifetime.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a) Ever-smoker: current or former?</td>
<td>Dropdown menu</td>
<td>Current smoker, Former smoker, Unknown</td>
<td>If patient is ever-smoker, record whether patient still smokes at time of baseline data collection (current smoker) or has quit smoking (former smoker).</td>
</tr>
<tr>
<td>Exposure history</td>
<td>02</td>
<td>What is the patient's alcohol consumption history?</td>
<td>Dropdown menu</td>
<td>Ever-drinker, Never-drinker, Unknown</td>
<td>Patient history of consuming alcoholic beverages. Ever-drinker ( \rightarrow ) Patient has had at least 12 alcoholic drinks in his or her lifetime, Never-drinker ( \rightarrow ) Patient has had fewer than 12 alcoholic drinks in his or her lifetime.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a) Ever-drinker: current or former</td>
<td>Dropdown menu</td>
<td>Current drinker, Former drinker, Unknown</td>
<td>If patient is ever-drinker, record whether patient still drinks alcohol at time of baseline data collection (current drinker) or no longer drinks alcohol (former drinker).</td>
</tr>
<tr>
<td>Exposure history</td>
<td>03</td>
<td>Does the patient have previous or current diagnosis of H. pylori infection?</td>
<td>Dropdown menu</td>
<td>Yes, No, Unknown</td>
<td>Indicator of whether patient has been diagnosed with past or/and current infection with H. pylori bacterium.</td>
</tr>
<tr>
<td>Exposure history</td>
<td>04</td>
<td>What is the patient's history of PPI usage?</td>
<td>Dropdown menu</td>
<td>Ever-user, Never-user, Unknown</td>
<td>Patient use of proton pump inhibitor (PPI) medications. Ever-user ( \rightarrow ) Patient has taken PPIs at some time, past or present, Never-user ( \rightarrow ) Patient has never taken PPIs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a) PPI ever-user: current or former?</td>
<td>Dropdown menu</td>
<td>Current user, Former user, Unknown</td>
<td>If patient is ever-user of PPIs, record whether patient still uses PPIs at time of baseline data collection (current user) or no longer takes PPIs (former user).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(i) Single or double-dose equivalent?</td>
<td>Dropdown menu</td>
<td>Single-dose, Double-dose, Unknown</td>
<td>If patient is current user of PPIs, record whether patient's PPI dosage is a single- or double-dose equivalent.</td>
</tr>
<tr>
<td>Exposure history</td>
<td>05</td>
<td>What is the patient's history of aspirin and/or NSAID usage?</td>
<td>Dropdown menu</td>
<td>Daily user, Occasional user, Never user, Unknown</td>
<td>Patient use of aspirin or NSAID medications. Daily user ( \rightarrow ) Patient takes aspirin or NSAIDs every day, Occasional user ( \rightarrow ) Patient takes aspirin or NSAIDs sometimes, but less often than every day, Never user ( \rightarrow ) Patient never takes aspirin or NSAIDs.</td>
</tr>
</tbody>
</table>
Table 4

Procedures
Repeated measures: Yes
Child of: Demographics/baseline

To add a procedure for a patient:
Endoscopy: table 4.1
Blood draw: table 4.2
Cytosponge: table 4.3
Esophagectomy: table 4.4

Table 4.1
Procedure: Endoscopy

<table>
<thead>
<tr>
<th>Table {skip logic}</th>
<th>#</th>
<th>Variable name</th>
<th>GUI format</th>
<th>Permissible values</th>
<th>Definition, disambiguation, or other data collection note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure: Endoscopy</td>
<td>01</td>
<td>Procedure type</td>
<td>Auto-filled</td>
<td>Endoscopy</td>
<td>This table records procedure type (\rightarrow) endoscopy</td>
</tr>
<tr>
<td>Procedure: Endoscopy</td>
<td>02</td>
<td>Date of procedure</td>
<td>Calendar</td>
<td>YYYY-MM-DD</td>
<td>Date of endoscopy procedure</td>
</tr>
<tr>
<td>Procedure: Endoscopy</td>
<td>03</td>
<td>Was BE (columnar epithelium) visible on endoscopy?</td>
<td>Dropdown menu</td>
<td>Yes, No, Unknown</td>
<td>Indicator of whether Barrett's esophagus visible on endoscopy</td>
</tr>
<tr>
<td>{skip if endoscopic BE != Yes}</td>
<td>(a) C (circumferential) value (cm)</td>
<td>Numerical</td>
<td>String (decimal)</td>
<td>If BE visible, record C (circumferential) value for extent of BE, in units of centimeters. Enter 999 for unknown.</td>
<td></td>
</tr>
<tr>
<td>{skip if C+M values are known}</td>
<td>(b) M (maximal) value (cm)</td>
<td>Numerical</td>
<td>String (decimal)</td>
<td>If BE visible, record M (maximal) value for extent of BE, in units of centimeters. Enter 999 for unknown.</td>
<td></td>
</tr>
<tr>
<td>{skip if C+M values are known}</td>
<td>(c) Length of BE segment (cm)</td>
<td>Numerical</td>
<td>String (decimal)</td>
<td>If BE visible, and C+M values not known, record length of BE segment, in units of centimeters. Enter 999 for unknown.</td>
<td></td>
</tr>
</tbody>
</table>
### Table 5

**Specimens**
Repeated measures: Yes  
Child of: Procedure

To add a specimen for a procedure:
- **Tissue**: table 5.1 (available for procedures: endoscopy, esophagectomy)
- **Blood**: table 5.2 (available for procedures: blood draw)
- **Cytology**: table 5.3 (available for procedures: endoscopy, cytospin)

#### Table 5.1
**Specimen: Tissue**
(Allowed procedures: endoscopy, esophagectomy)

<table>
<thead>
<tr>
<th>#</th>
<th>Variable name</th>
<th>GUI format</th>
<th>Permissible values</th>
<th>Definition, disambiguation, or other data collection note</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Specimen type collected</td>
<td>Auto-filled</td>
<td>Tissue</td>
<td>This table records specimen type → tissue. Method of obtaining tissue specimen: For esophagectomy specimen, ‘Esophagectomy’ must be selected. This is not a valid value for endoscopic specimens.</td>
</tr>
<tr>
<td>02</td>
<td>Specimen collection procedure</td>
<td>Dropdown menu</td>
<td>Forcep biopsy, Endoscopic mucosal resection (EMR), Esophagectomy</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Specimen type(s) stored</td>
<td>Checkboxes</td>
<td>Preserved tissue (frozen or fixed), Derived DNA, Derived RNA</td>
<td>Record all types of specimen and derivative material stored from tissue specimen collection.</td>
</tr>
<tr>
<td>04</td>
<td>Specimen tissue of origin</td>
<td>Dropdown menu</td>
<td>Barrett’s esophagus, Barrett’s esophagus, recurrent post-ablation esophagus, Squamous esophagus, Neosquamous esophagus, Gastro-esophageal junction, Gastric cardia, Duodenum, Various (esophagectomy), Other</td>
<td>Anatomical region/organ and/or tissue type from which specimen was obtained. For esophagectomy specimen, ‘Various (esophagectomy)’ must be selected. This is a valid value for endoscopy specimens. If various samples are taken on endoscopy, a separate specimen record should be entered for each separate specimen.</td>
</tr>
<tr>
<td></td>
<td>(skip if tissue of origin ≠ BE, recurrent)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(a) Recurrent BE: Number of follow-up examinations with negative findings, between final ablative session and finding of recurrent BE</td>
<td>Numeric</td>
<td>Integer</td>
<td>If specimen tissue of origin is recurrent BE, record number of follow-up examinations with negative findings between final ablative session and finding of recurrent BE. Enter 999 for unknown. Exam with negative findings → exam in which a biopsy sample is taken, and biopsy shows metaplasia (or higher) in esophagus, and no dysplasia in gastric cardia.</td>
</tr>
<tr>
<td>Table (skip logic)</td>
<td>#</td>
<td>Variable name</td>
<td>GUI format</td>
<td>Permissible values</td>
</tr>
<tr>
<td>------------------</td>
<td>---</td>
<td>---------------</td>
<td>------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>(skip if tissue of origin != BE*)</td>
<td>(b)</td>
<td>(1) BE: distance from incisors (cm)</td>
<td>Numeric</td>
<td>String (decimal)</td>
</tr>
<tr>
<td>(skip if focal BE != Yes)</td>
<td>(b)</td>
<td>(2) BE: focal lesion?</td>
<td>Dropdown menu</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>(skip if tissue of origin != squam or neosquamous)</td>
<td>(i)</td>
<td>Focal BE lesion: clock location</td>
<td>Numeric</td>
<td>1-12</td>
</tr>
<tr>
<td>(skip if tissue of origin != gastric cardia)</td>
<td>(c)</td>
<td>Squamous or neosquamous esophagus: distance from incisors (cm)</td>
<td>Numeric</td>
<td>String (decimal)</td>
</tr>
<tr>
<td>(skip if tissue of origin != duodenum)</td>
<td>(d)</td>
<td>(1) Gastric cardia: curvature</td>
<td>Dropdown menu</td>
<td>Greater, Lesser, Unknown</td>
</tr>
<tr>
<td></td>
<td>(d)</td>
<td>(2) Gastric cardia: A/P</td>
<td>Dropdown menu</td>
<td>Anterior, Posterior, Unknown</td>
</tr>
<tr>
<td></td>
<td>(d)</td>
<td>(3) Gastric cardia: laterality</td>
<td>Dropdown menu</td>
<td>Right, Left, Unknown</td>
</tr>
<tr>
<td></td>
<td>(e)</td>
<td>Duodenum: portion</td>
<td>Dropdown</td>
<td>Duodenal bulb, Second portion, Unknown</td>
</tr>
</tbody>
</table>

**Specimen: Tissue**

| 05 | Highest pathology associated with procedure in which specimen was obtained | Dropdown menu | Normal squamous and/or normal gastric cardia, Non-erosive esophagitis, Erosive esophagitis, Specialized intestinal metaplasia (SIM), Indefinite, Low-grade dysplasia (LGD), High-grade dysplasia (HGD), Adenocarcinoma (EAC), Unknown | Highest pathology seen on endoscopic procedure or esophagectomy in which specimen obtained. For esophagectomy, value selected must be 'Adenocarcinoma'. Hierarchy of pathologies: normal < non-erosive esophagitis < erosive esophagitis < SIM < indefinite < LGD < HGD < EAC |
Table 5.2
Specimen: blood
Allowable procedure: blood draw

<table>
<thead>
<tr>
<th>Variable name</th>
<th>GUI format</th>
<th>Permissible values</th>
<th>Definition, disambiguation, or other data collection note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen type collected</td>
<td>Auto-filled</td>
<td>Blood</td>
<td>This table records specimen type → blood</td>
</tr>
<tr>
<td>Specimen type(s) stored</td>
<td>Checkboxes</td>
<td>Whole blood, Serum, Plasma, Buffy coat, Derived DNA, Derived RNA</td>
<td>Record all types of specimen and derivative material stored from blood specimen collection.</td>
</tr>
<tr>
<td>Highest pathology associated with endoscopic examination performed contemporaneous with obtaining specimen</td>
<td>Dropdown menu</td>
<td>Normal squamous and/or normal gastric cardia, Non-erosive esophagitis, Erosive esophagitis, Specialized intestinal metaplasia (SIM), Indefinite, Low-grade dysplasia (LGD), High-grade dysplasia (HGD), Adenocarcinoma (EAC), Unknown, Endoscopy not performed at time of specimen collection</td>
<td>Hierarchy of pathologies: normal &lt; non-erosive esophagitis &lt; erosive esophagitis &lt; SIM &lt; indefinite &lt; LGD &lt; HGD &lt; EAC</td>
</tr>
<tr>
<td>Specimen available for use?</td>
<td>Dropdown menu</td>
<td>Yes, No</td>
<td>Indicator of whether specimen is available for use by other investigators</td>
</tr>
<tr>
<td>(b) Local specimen identifier code</td>
<td>Comment box</td>
<td>Character string</td>
<td>If specimen available for use, record local specimen identifier code</td>
</tr>
<tr>
<td>(c) Specimen depleted, lost, or otherwise no longer available for use?</td>
<td>Dropdown menu</td>
<td>Yes, No</td>
<td>If specimen available for use at one time is lost, depleted, or otherwise no longer available for use, change value of this variables from 'No' to 'Yes'</td>
</tr>
<tr>
<td>#</td>
<td>Variable name</td>
<td>GUI format</td>
<td>Permissible values</td>
</tr>
<tr>
<td>----</td>
<td>------------------------------------------</td>
<td>--------------------------</td>
<td>------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>01</td>
<td>Specimen type collected</td>
<td>Auto-filled</td>
<td>Cytology</td>
</tr>
<tr>
<td>02</td>
<td>Specimen collection procedure</td>
<td>Dropdown menu</td>
<td>Brush biopsy, Cytosponge, Fine needle aspiration (FNA)</td>
</tr>
<tr>
<td>03</td>
<td>Specimen type(s) stored</td>
<td>Checkboxes</td>
<td>Slide, Pellet, Derived DNA, Derived RNA</td>
</tr>
<tr>
<td>04</td>
<td>Specimen tissue of origin</td>
<td>Dropdown menu</td>
<td>Barrett’s esophagus, Barrett’s esophagus, recurrent post-ablation, Squamous esophagus, Neosquamous esophagus, Gastro-esophageal junction, Gastric cardia, Duodenum, Lymph node, Various (cytospunge scraping), Other</td>
</tr>
</tbody>
</table>

(skip if specimen tissue of origin = BE, recurrent)

(a) Recurrent BE: Number of follow-up examinations with negative findings, between final ablative session and finding of recurrent BE       Numeric Integer

Exam with negative findings → Exam in which a biopsy sample is taken, and biopsy shows metaplasia (or higher) in esophagus, and no dysplasia in gastric cardia
## Table 6

### Outcomes

Repeated measures: No
Child of: Demographics/baseline

<table>
<thead>
<tr>
<th>#</th>
<th>Variable name</th>
<th>GUI format</th>
<th>Permissible values</th>
<th>Validation (hard or soft stop) or other development note</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Progression to cancer?</td>
<td>Dropdown menu</td>
<td>Yes, No, Unknown (patient is lost to follow-up)</td>
<td>Indicator of patient progression to cancer. Change value to 'Yes' if/when patient progress to cancer.</td>
</tr>
<tr>
<td></td>
<td>(a) Date of cancer diagnosis</td>
<td>Calendar</td>
<td>YYYY-MM-DD</td>
<td>If patient progresses to cancer, record date of cancer diagnosis</td>
</tr>
<tr>
<td></td>
<td>(b) Final path report available</td>
<td>Dropdown menu</td>
<td>Yes, No, Unknown</td>
<td>If patient progresses to cancer, indicator of whether patient's final path report is available</td>
</tr>
<tr>
<td></td>
<td>Deceased?</td>
<td>Dropdown menu</td>
<td>Yes (patient has died), No (patient's last known vital status is alive), Unknown (patient is lost to follow-up)</td>
<td>Indicator of patient death during follow-up. Change value to 'Yes' if/when patient dies during follow-up.</td>
</tr>
<tr>
<td></td>
<td>(a) Date of death</td>
<td>Calendar</td>
<td>YYYY-MM-DD</td>
<td>If patient has died, record date of death</td>
</tr>
<tr>
<td></td>
<td>(b) Cause of death (relative to esophageal malignancy)</td>
<td>Dropdown menu</td>
<td>Directly related, Indirectly related, Not related, Unknown</td>
<td>If patient has died, record whether cause of death is known to be directly, indirectly, or not related to esophageal malignancy</td>
</tr>
</tbody>
</table>
Where Are We? (i2b2)
(Slide courtesy of Chris Shafer)

- 2.6M deidentified encounters from various parts of JHM – no JHCP data currently
- No Epic data yet – we are working through the planning and approval gateways
- The last five years of numerical lab data (text and complex labs eventually)
- Billing diagnosis and procedure codes – with all associated caveats
- Demographics – age is bucketed to 10 year brackets for high level search
caTissue i2b2 Integration

INFORMATICS SHARED RESOURCE

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The Informatics Shared Resource (ISR) serves as a biomedical research informatics resource for KCC’s basic, clinical, and translational investigators. This support includes infrastructural provisioning, software development or acquisition, and consultative collaboration. ISR services are available directly to peerreviewed funded cancer investigators, or indirectly to other cancer center core facilities, thereby providing services to all program members. The ISR also provides informatics support for the clinical research activities of the Jefferson Kimmel Cancer Center Network of community hospitals.
Thank You!

- Questions?
References:


- **National Cancer Institute**, **Best Practices for Biospecimen Resources 2007**

References:

- Federal Register / Vol. 71, No. 82 / Friday, April 28, 2006. First-Generation Guidelines for NCI Supported Biorepositories
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