OPENSPECIMEN USE AT UNIVERSITY OF UTAH

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- Shelby-Jade Murdock, Clinical Data Integration
- Nwamaka Flora Ohiku, Research Informatics Specialist
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CTSI GOAL

• Catalog all specimens owned by the University
• Build collaborations
  – within the University
  – nationwide/worldwide
• Usefulness:
  – Link specimens to clinical data: standard vocabulary
  – Link to consent statements
3 TYPES OF SUPPORTED IMPLEMENTATIONS

• Individual collections and storage
• Biorepositories
  – Departments
  – Research groups
• Core Laboratory processing and storage
  – Current
    • Specimen-centric protocols managed by the Core staff
      – Accession, processing, and storage
      – Legacy storage projects
    • PI managed protocols
      – Submit samples for processing to CTRC
      – Specimens stored at CTRC or returned to PI lab for storage/use
    • Special processing workflows: iPSC, CRISPR: Protocol groups
  – Future
    • All protocols to be designed and managed by PI lab
LABORATORY WORKFLOW
TYPES OF INDIVIDUAL WORKFLOWS

• Single local site managing participant registration and sample storage
  – Can follow standard OS workflows

• Local lab is a Site in a multi-site study
  – Processes defined and set by external source
  – Limits flexibility
  – Must design workflow to fit predesigned, NIH-defined, process
  – Participant registration is in external LIMS (or REDCap)
MULTI-SITE STUDIES: WORKFLOW TYPES

• **Central Biorepository (external)**
  - Samples collected here, shipped to central lab at intervals
    • Extra samples collected and stored for use locally
    • Need to link participants to Study ID for eventual linkage to clinical data
  - Samples shipped directly
  - Samples are processed and then shipped off-site

• **Local Biorepository**
  - Participants registered and samples collected according to established DCC protocol, pass through central lab.
  - Samples shipped to local BR for permanent management
    • Kit or Requisition ID
    • Link barcoded samples with minimal metadata (type, qty)
WORKFLOW FOR MULTI-SITE STUDIES

- Study design
- Data plan
- Specimen plan

Study design
Data plan
Specimen plan

• Recruitment
• Sample collections

DCC

Site 1
Site 2
Site 3
Site 4

Central Lab

Off-site Central Lab

Processing Analyses

Analyze clinical data

Researchers

Request samples

Approve request

Kits

Samples

Missing link

Permanent storage

Ship samples

Data
WORKFLOW FOR MULTI-SITE STUDIES

- Study design
- Data plan
- Specimen plan

DCC

Site 1

Site 2

Site 3

Site 4

Request samples

Analyze clinical data

Approve request

Researchers

Missing link: OpenSpecimen

Ship samples

Off-site Central Lab

Central Lab

Processing Analyses

Permanent storage

Data

Recruitment

Sample collections

kits

Sample collections
INTERIM PROCESS FLOW FOR CTRC

Sample submission
- Lab ID
- Type
- Qty
- Process

Process to Derivatives
- Accession
- Process
- Metadata
- Store

Return / Store
- Lab retrieves
- CTRC Ships
- Transfer to biorepository

REDCap Project

OpenSpecimen: Specimen-centric protocol
INITIAL GOAL: BILL FOR CONTAINER STORAGE

• Count containers per project for billing
  – Create CP for all projects being billed
  – Map all existing boxes in freezers
  – Assign each box to CP
  – Query: count boxes per project per freezer type (-80 vs LN2)
  – Invoice: $$ * #_containers per freezer type
<table>
<thead>
<tr>
<th>CTSI ID</th>
<th>Billing Code</th>
<th>Investigator</th>
<th>Department</th>
<th>Project Title</th>
<th>Container Name Count</th>
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<tbody>
<tr>
<td>1017</td>
<td>01-00237-200...</td>
<td>Adhish Agarwal</td>
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<td>ERES-HFpEF (18-26) 1071</td>
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<td>1313</td>
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<td>Tanya Hallicd</td>
<td>Health and Kinesiology</td>
<td>CTSI CTRC Protocol 18-...</td>
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<td>1403</td>
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<td>James Beck</td>
<td>Orthopaedics</td>
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<td>2051</td>
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<td>Neklason Lab</td>
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<td>2254</td>
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<td>Dustin Williams</td>
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<td>Heterotopic Ossification ...</td>
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<td>354</td>
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<td>Brett Burton</td>
<td>Scientific Computing an...</td>
<td>OrthodontiCal:Signal O...</td>
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<td>3561</td>
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<td>Adam Spivak</td>
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<td>UHCQ Biorepository (Pa...</td>
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<tr>
<td>364</td>
<td>01-01486-500...</td>
<td>Joseph Stanford</td>
<td>Public Health</td>
<td>Utah Children's Project ...</td>
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</table>
PROBLEMS

• Legacy protocols with no samples mapped
  – Containers are invisible to the query if no samples are in the box
  – Created ‘ghost’ samples in the CP and assigned one per box: type recorded as ‘Fluid’ if not known

• Samples from 2 CPs mixed in one box
  – Boxes are counted more than once. Had to create a specific query for those affected CPs.

• Oversized boxes / bags:
  – organized to one shelf.
  – New query: count containers on shelf
  – Add surcharge to invoice per project
## CUSTOMIZED CP EXAMPLE: SCRN

<table>
<thead>
<tr>
<th>Pregnancy ID</th>
<th>Study ID</th>
<th>Cohort</th>
<th>Type of gestation</th>
<th>Enrollment</th>
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<td>Y4926</td>
<td>242135U</td>
<td>all live birth outcome</td>
<td>singleton</td>
<td>enrolled once</td>
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<tr>
<td>Y8385</td>
<td>242134W</td>
<td>all live birth outcome</td>
<td>singleton</td>
<td>enrolled once</td>
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</tbody>
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### Events

- Maternal Blood Draw (MAT)
- Delivery (DLV)
- Placental Pathology (PLAC)
- Fetal Postmortem (FETAL)
- Fetal Neuropathology (NEURO)
**Requirements Set by Descriptions**

<table>
<thead>
<tr>
<th>Events</th>
<th>Frozen Tissue from Placenta (Placental Disc Section 4)</th>
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<tbody>
<tr>
<td>Maternal Blood Draw (MAT)</td>
<td>Frozen Tissue</td>
</tr>
<tr>
<td>Delivery (DLV)</td>
<td>Frozen Tissue from Placenta (Placental Disc Section 4)</td>
</tr>
<tr>
<td>Placental Pathology (PLAC)</td>
<td>Swab collected in Cryovial (4mL) (Placental membrane swab - DNA)</td>
</tr>
<tr>
<td>Fetal Postmortem (FETAL)</td>
<td>Swab</td>
</tr>
<tr>
<td>Fetal Neuropathology (NEURO)</td>
<td>Fixed Tissue Block from Umbilical Cord (Umbilical cord - proximal)</td>
</tr>
<tr>
<td>Add Event...</td>
<td>Fixed Tissue Block from Umbilical Cord (Umbilical cord - distal)</td>
</tr>
<tr>
<td></td>
<td>Fixed Tissue Block from Placental Membrane (Membrane Roll)</td>
</tr>
<tr>
<td></td>
<td>Fixed Tissue Block from Placenta (Parenchyma at UC insertion site)</td>
</tr>
<tr>
<td></td>
<td>Derived Fixed Tissue Slide (Standard disc)</td>
</tr>
<tr>
<td></td>
<td>Derived Fixed Tissue Curl (Standard disc)</td>
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<tr>
<td></td>
<td>Fixed Tissue Block from Placenta (Focal lesions)</td>
</tr>
<tr>
<td></td>
<td>Fixed Tissue Block from Placenta (Diffuse lesions)</td>
</tr>
<tr>
<td></td>
<td>Fixed Tissue Block from Dividing membrane (Dividing membrane)</td>
</tr>
</tbody>
</table>

*UTAH CTSI*

**CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE**
# EXAMPLE OF TISSUES COLLECTED

## Occurred Visits

<table>
<thead>
<tr>
<th>Event Name</th>
<th>Visit Name</th>
<th>Visit Date</th>
<th>Sample Origin</th>
<th>Placental Disc ID</th>
<th>Collection Stats</th>
<th>Utilization Stats</th>
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</thead>
<tbody>
<tr>
<td>Maternal Blood Draw</td>
<td>Y6825_MAT</td>
<td>Apr 24, 2008</td>
<td>0 - Mother</td>
<td>Not Specified</td>
<td>3</td>
<td>19</td>
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<tr>
<td>Delivery</td>
<td>Y6825_DLV1</td>
<td>Apr 24, 2008</td>
<td>1 - Live birth</td>
<td>Not Specified</td>
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<td>1</td>
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<tr>
<td>Delivery</td>
<td>Y6825_DLV2</td>
<td>Apr 24, 2008</td>
<td>2 - Stillborn</td>
<td>Not Specified</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Placental Pathology</td>
<td>Y6825_PLAC2</td>
<td>Apr 24, 2008</td>
<td>2 - Stillborn</td>
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<td>Placental Pathology</td>
<td>Y6825_PLAC1</td>
<td>Apr 24, 2008</td>
<td>1 - Live birth</td>
<td>AB</td>
<td>19</td>
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<tr>
<td>Fetal Postmortem</td>
<td>Y6825_FETAL1</td>
<td>Apr 24, 2008</td>
<td>2 - Stillborn</td>
<td>Not Specified</td>
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<tr>
<td>Fetal Neuropathology</td>
<td>Y6825_NEURO1</td>
<td>Apr 24, 2008</td>
<td>2 - Stillborn</td>
<td>Not Specified</td>
<td>7</td>
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</table>
QUERY EXAMPLE;
FETAL SPECIMENS FROM NEUROPATH

<table>
<thead>
<tr>
<th>Pregnancy ID</th>
<th>Specimen Label</th>
<th>Specimen Type</th>
<th>Sample Description</th>
<th>Anatomic Site</th>
<th>Visit name</th>
<th>Sample origin</th>
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<tbody>
<tr>
<td>Y0005</td>
<td>4029617H-000</td>
<td>Fixed Tissue Block</td>
<td>Cerebellum and brain</td>
<td>Not Specified</td>
<td>Y0005_NEURO1</td>
<td>1 - Stillborn</td>
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<td>Y0005</td>
<td>4029614N-000</td>
<td>Fixed Tissue Block</td>
<td>Cortical tissue</td>
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<td>Y0005_NEURO1</td>
<td>1 - Stillborn</td>
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<td>Y0005</td>
<td>4029615L-000</td>
<td>Fixed Tissue Block</td>
<td>White matter</td>
<td>Subcortical tissue (...</td>
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<td>Cortical tissue</td>
<td>Cortical tissue (grey ...</td>
<td>Y0110_NEURO1</td>
<td>1 - Stillborn</td>
</tr>
</tbody>
</table>
PROSPECTIVE STUDY

• Determine workflow
• Design Events
• Set participant, visit, specimen labels
• Standard workflow
• Design physical labels
LEGACY STUDIES

• Data organization
• How to represent specimens in logical manner
• Is there a need to customize the interface?