Josh Sommer
Simone Sommer, MD, MPH

Banking on a Cure
Chordoma Community Conference 2009
Scientific Resources

**Model Systems**
- Cell Lines
- Transgenic Animals
- Xenographs...

**Clinical Data**
- Treatment History
- Family History
- Tests & Images...

**Biospecimens**
- Tumor Tissue
- Blood
- DNA...

**“Omic” Data**
- Gene Sequence
- Gene Expression
- Protein Expression...
**Vision:** a centralized repository of tumor, blood, and DNA samples connected to a continually-growing set of clinical and biological data

- An immediate source of tissue to meet the needs of the research community
- A long-term bank to accumulate samples
  - Will allow recurrences to be compared with primary tumors
  - Will allow analyses that require large sample size
Making it Happen

• Studied biobanking throughout 2008
• Jan 2009, recruited Wayne Beyer, PhD
  - 15 years experience working with human tissue in industry and academia
  - Adjunct faculty member at Duke Univ. Pathology Department
  - Senior Research Fellow at Duke Institute for Genome Sciences and Policy

• Wayne helped map out the project, identify needs, and evaluate options
  - 43 candidate biobanks identified
  - 30 biobanks contacted
  - 20 in-depth profiles
  - 11 facilities visited
  - 10 proposals/quotes obtained
  - 5 selected for serious consideration
Making it Happen
## Road Trips - Time for Site Visits – Lot’s of Questions to Ask and Audit!

<table>
<thead>
<tr>
<th>Clinical Site Related Infrastructure</th>
<th>Sample Processing Infrastructure</th>
<th>Sample Analysis</th>
<th>Sample Storage Infrastructure</th>
<th>Information Technology Infrastructure</th>
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<tbody>
<tr>
<td>Patient Outreach Program</td>
<td>Standard Operating Procedures (SOPs)</td>
<td>Standard Operating Procedures (SOPs)</td>
<td>HVAC</td>
<td>Power Backup</td>
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<td>Patient donation hotline</td>
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<td>Access Control</td>
<td>Alternate site storage Data</td>
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<td>Security Systems</td>
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<td>PB-Informed Consent Network</td>
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<td>Fire Prevention Systems</td>
<td>Inventory Management</td>
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<td>IRB Management &amp; Approval</td>
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<td>backup storage / capacity</td>
<td>Sample History</td>
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<tr>
<td>Network Standard Nomenclature (e.g. SNOMED, csBIG) Medical records</td>
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<td>alternate storage sites</td>
<td>Research Data Repository</td>
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<td>Clinical Site Training</td>
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<td>Storage time QA/QC</td>
<td>Internet Access / Query</td>
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<td>Material Transfer Agreements</td>
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<td>Storage (other)</td>
<td>Sample Receipt / Distribution</td>
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<td>Site Selection, Management</td>
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<td>Storage (slide)</td>
<td>Inventory Searchable</td>
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<td>Site Approval, Activation</td>
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<td>Storage (80)</td>
<td>Barcoding</td>
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<td>Site Monitoring</td>
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<td>Store non-human tissue (safeguards)</td>
<td>Quality Procedures</td>
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<td>Sample Collection Protocols</td>
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<td>Monitoring Systems</td>
<td>Internal Quality Program</td>
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<tr>
<td>Sample Collection Capabilities</td>
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<td>Cell Line Construction</td>
<td>Web-based tracking systems that can be used to verify</td>
</tr>
<tr>
<td>Minor Sample Processing</td>
<td></td>
<td></td>
<td>Flow Cytometry</td>
<td>specimen arrival, processing, storage, and distribution</td>
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<tr>
<td>Sample validation / Quality Assurance</td>
<td>In house Board Certified Pathologist Review</td>
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<td>Nucleic Acid (NA) Extraction (DNA/RNA)</td>
<td>QA Program</td>
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<tr>
<td>Sample Transport / Storage Devices (i.e. dev)</td>
<td>Receiving Protocols</td>
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<td>DNA/RNA Quality analysis (i.e. size: i.e. nucleic acid)</td>
<td>QC Program</td>
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<td>Transport / Shipping protocols</td>
<td>Transport, Shipping protocols</td>
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<td>Web-hosting of all sample and clinical data</td>
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<td>Shipping Manifest</td>
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<td>Cell Line construction</td>
<td>Web-based tracking systems that can be used to follow sharing</td>
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<td>Shipping Logs</td>
<td>Shipping Notification</td>
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<td>Flow Cytometry</td>
<td>and distribution of specimens / data resources</td>
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<tr>
<td>Inventory Management</td>
<td>Shipping Verification</td>
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<td>Nucleic Acid Extraction</td>
<td>Quality Assurance / Quality Control</td>
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<td>Appropriate sample Storage</td>
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<td>Management Track Record</td>
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<tr>
<td>Rights to retain samples / move samples to alternate location</td>
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<td>Flow Cytometry</td>
<td>Adequate Staging</td>
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<tr>
<td>Quality Assurance / Quality Control</td>
<td>Collection kit distribution for blood, tissues, DNA, RNA</td>
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<td>Audit / Experience / Say</td>
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<td>Staff Experience</td>
<td>Sample accessioning and management</td>
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<td>storage containers (devs, etc.)</td>
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<td>Audit / Experience / Say</td>
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<td>Flow Cytometry</td>
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<td>Flow Cytometry</td>
<td>Sample Coding / BarCoding</td>
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<td>Equip maintenance / repair logs</td>
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*Note: The table continues with similar entries for Molecular Biology / Genomic Analysis, Proteomic Analysis / Protein Chemistry, and Quality Assurance / Quality Control.*
### Detailed Analysis

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<th>SeraCare</th>
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<td>IRB/Consent Form Templates or assistance</td>
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<td>Blood fractionation</td>
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### Final Decision & Implementation

- Retained biobanking expert Kelly Feil as consultant to
  - Finalize selection
  - Negotiate contract
  - Establish protocol
  - Find and collect tumors
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
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<tbody>
<tr>
<td>» Finalize Contract with Biobank Facility</td>
<td>Mid Jul</td>
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<tr>
<td>» Formalize Biobank procedures and submit protocol to Institutional</td>
<td>Early Aug</td>
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<tr>
<td>Review Board for ethics approval</td>
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<tr>
<td>» Hire Biobank coordinator</td>
<td>Mid Aug</td>
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<tr>
<td>» Begin pilot phase specimen collection</td>
<td>Early Sep</td>
</tr>
<tr>
<td>» Establish collection protocols at partner hospitals</td>
<td>Mid Sep</td>
</tr>
<tr>
<td>» Begin enrollment in clinical data registry</td>
<td>Early Oct</td>
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<tr>
<td>» Begin open enrollment in Biobank</td>
<td>Late Nov</td>
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<tr>
<td>Specimen</td>
<td>Purpose</td>
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<td>---------------------</td>
<td>-------------------------------------------------------------------------</td>
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</tbody>
</table>
| Medical information | • Identify patterns of response  
                   • Discover prognostic factors  
                   • Correlate outcome with tumor biology |
| treatment history, response to therapy, outcome |                                           |
| Tumor tissue        | • Study tumor biology  
                   • Discover therapeutic targets  
                   • Identify molecular subtypes |
| fresh, frozen, fixed |                                           |
| Blood or Saliva     | • Obtain germ-line DNA  
                   • Identify biomarkers that predict recurrence |
<p>| before and after surgery |                                           |</p>
<table>
<thead>
<tr>
<th>Informed Consent</th>
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<tbody>
<tr>
<td>» know what you are participating in</td>
</tr>
<tr>
<td>» weigh the potential risks and benefits</td>
</tr>
<tr>
<td>Medical information</td>
</tr>
<tr>
<td>Complete medical and family health history questionnaire</td>
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<tr>
<td>and transfer relevant medical records to the registry</td>
</tr>
<tr>
<td>Tumor tissue</td>
</tr>
<tr>
<td>Notify CF staff of upcoming surgery, and we’ll work with the hospital to obtain</td>
</tr>
<tr>
<td>excess tissue for research</td>
</tr>
<tr>
<td>Blood and Saliva</td>
</tr>
<tr>
<td>CF will send you a collection kit to take to your primary care physician for</td>
</tr>
<tr>
<td>blood-drawing. Alternatively we can also send a kit for you to spit into.</td>
</tr>
</tbody>
</table>

Call 919-809-6779 or email biobank@chordoma.org