The Importance of Best Practices to Patients, Advocates & The Public

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TRAC - Translating Research Across Communities
NCI Biospecimen Best Practices Forum
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Office of Biorepositories and Biospecimen Research
National Cancer Institute - National Institutes of Health
U.S. Department of Health and Human Services
Across The Scientific Spectrum

Physical
Behavioral
Social
Cultural
Economic
Political
Spiritual
Technological

HOPE
"From the standpoint of medicine as an art for the preparation and cure of disease, the man who translates the hieroglyphics of science into the plain language of healing is certainly more useful."

-William Osler, Physician
100 Years and Counting...

- It has taken more than a century, but the marrying of biospecimens, technology, and science for patient benefit is coming of age.
- Biospecimens are precious human resources filled with unique genetic information.
- The privilege of using these resources to advance and translate research into clinical application for patient progress brings great responsibility not to be taken lightly.
- Biospecimens are part of resource toolkit.
U.S. Cancer Mortality Rates

Getting a New Product Through This Process Is Not Easy... Many Years and Lots of $$$
Patient Dilemma with Words and Decisions...

Invasive ? Non-invasive?
Academic Center ? Local ?
Informed Consent?
Do my kids need genetic testing?
Where is my tissue?
Eligible ? Insurance ?
Am I Going to Live?

Personalized medicine?
Biospecimen?
Targeted Therapies?
EGFR Inhibitor? Biopsy?
Proteomics?
The Promise

- Targeted Therapies
- Seek and Control instead of Search and Destroy
- Genetic Testing
- Reduced Toxicities
- Predictive/Preventive Capability
- Reduced drug failure rates
- A CURE
All Drugs Are Targeted Therapies

- The problem is the numbers of compounds AND targets known to work together well are few and far between...here are a few examples of working ones

- Trastuzumab-Herceptin® \(\rightarrow\) HER 2
- Cetuximab-Erbitux® \(\rightarrow\) EGFR
- Imatinib mesylate-Gleevec® \(\rightarrow\) KIT
- Erlotinib-Tarceva® \(\rightarrow\) EGFR
Connect The Dots

Research: Patients, Volunteers, Groups & Public

Research: Academic & Community

Research: Industry & Private Sector

Research: Public Agencies & Policy Makers
Why We Need To Keep Moving In the Right Direction

- Information is not knowledge
- Competing Funding Priorities
- More Survivors; Still Feared
- Shrinking Budgets
- Increased Regulations
- Fast Moving Science
- Requirements and Expectations
<table>
<thead>
<tr>
<th>Risk</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>Federal Law</td>
<td>State Law</td>
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<tr>
<td>HIPAA; IRB;</td>
<td>Common Rule</td>
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<td>Black Letter Law</td>
<td>Common Sense</td>
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<td>Benefit</td>
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<td>Simplification</td>
<td>Complication</td>
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<td>Misuse</td>
<td>Appropriate</td>
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<td>No patient uptake</td>
<td>No participation</td>
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<td>No biospecimens</td>
<td>No research</td>
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<td>No progress</td>
<td>No answers</td>
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<td>No cures</td>
<td>No hope</td>
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Earning Public Trust & Confidence

Confidence in you and your team
Confidence in the reason
Confidence in the test
Confidence in the system
Confidence in the procedure
Confidence in the test results
Confidence in the diagnosis
Confidence in the recommendation
Confidence in the outcome
Confidence...period
Biospecimen Best Practices Are More Than Just Freezer Temperature and Hold Time

- Partnering with the public
- Privacy and patient protection
- Data Sharing and bioinformatics
- Handling of biospecimens
- Promoting access for research
- Intellectual property
- Future patient access to sample
- Intellectual Property
Consequences of Poor Practices

- False + and False -
- Inaccuracy; non-reproducibility
- Erodes public confidence
- Wastes time & money
- Impedes clinical benefit
- Takes another 100 Years
Practice, Process, Performance = Product

- Joist
- Fascia
- 200 psi
- 4 in 12
- 20/30 finish
- Romex
- Title 24
- Combi
- TJI

- Is the footing designed to carry a live load of 100 lbs PSF?
- Do you nail drywall at 6” o.c. or 12” o.c?
- Does the concrete cure for 28 or 40 days?
- Imagine making choices and decisions that affect our lives…without access to guidance, information, and resources?
- Imagine trying to build your dream house without well designed plans and standards or a qualified architect or builder..
- BEST PRACTICES, STANDARDS AND BLUEPRINTS ARE CRUCIAL WHETHER IT’S A HOUSE OR A BIOSPECIMEN!
Benefits for All

Commitment for:
Infrastructure + resources + best practices
can yield high-quality biospecimens

The Potential Upside

*data with integrity* that becomes information
transformed into *knowledge* that puts real
*discovery* into real life in real time for
*patient benefit*
Research Advocates: Partners In Progress

- Scientific committees
- Clinical trial design
- IRB; Data Safety Monitoring Board
- Grant Review
- Biospecimens
- Bring The Patient Perspective
“We must harness the scientific, industrial, and social will to accelerate discoveries into accessible and meaningful clinical applications. Patients, families, friends, and loved one are counting on us...Because in the end, it’s not about you, or me, or the science, it’s about the patient.”

Paula Kim - Research & Patient Advocate
Patient & Advocate Perspectives

Don’t Leave Home Without Them