

# **Informatics-guided workflow for procuring biospecimens from cancer patients**

**3rd Annual Biospecimen Research Network (BRN) Symposium:  
Advancing Cancer Research Through Biospecimen Science**

OBRR, NCI

Bethesda, MD 2010

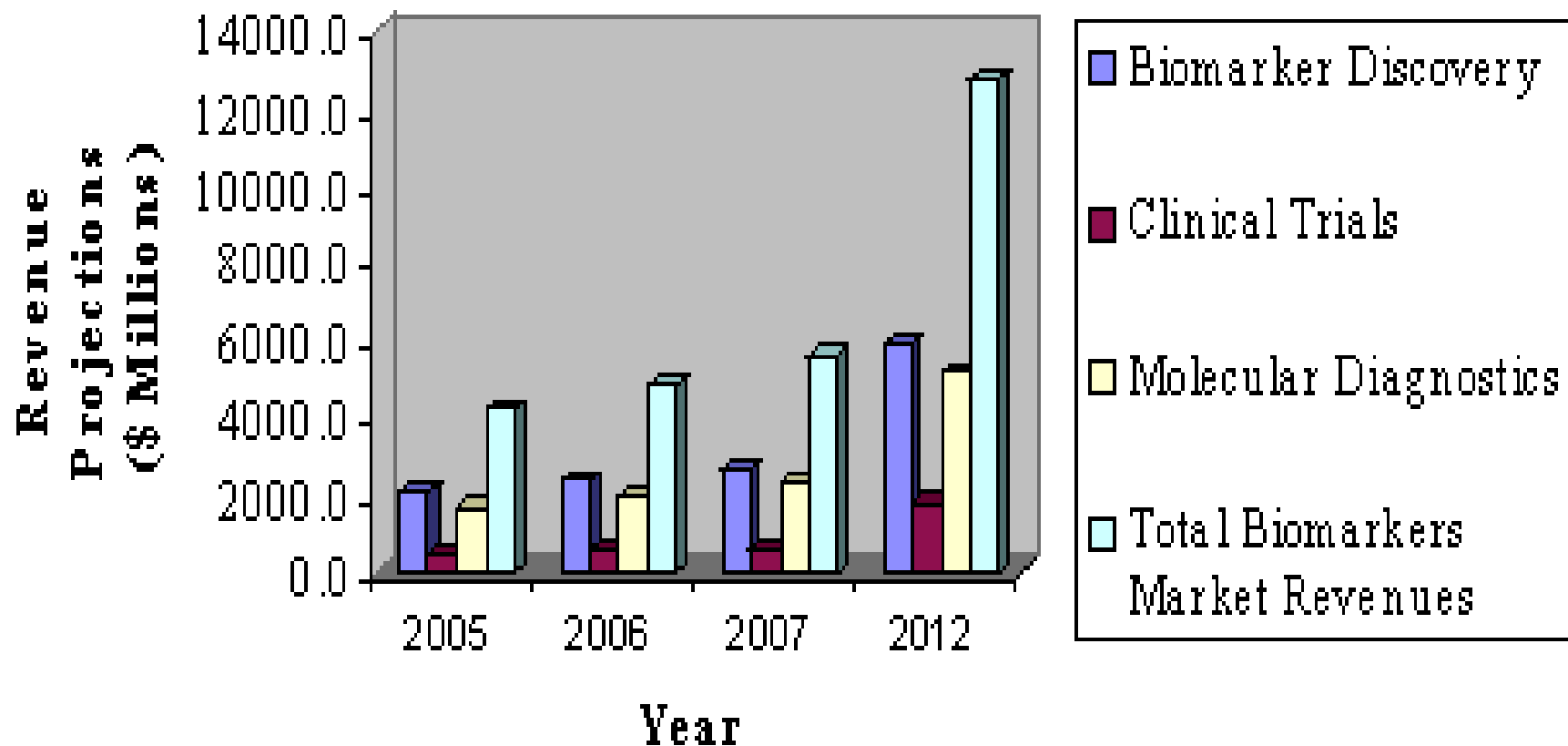
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**Tissue Bank and Cancer Research Program**

**Cancer Center**

**Hackensack University Medical Center**

## Demands for basic, translational and clinical science related to biomarkers will dramatically increase in the future

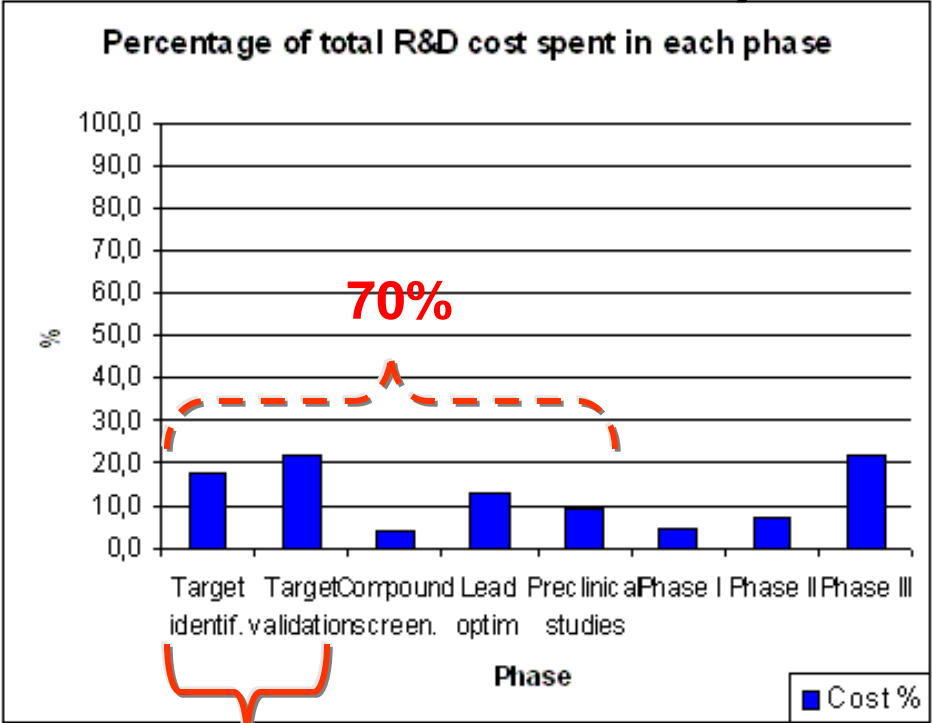


Source: BCC Research, 2007

**Biomarkers: The Expanding Global Market (BIO61A)**

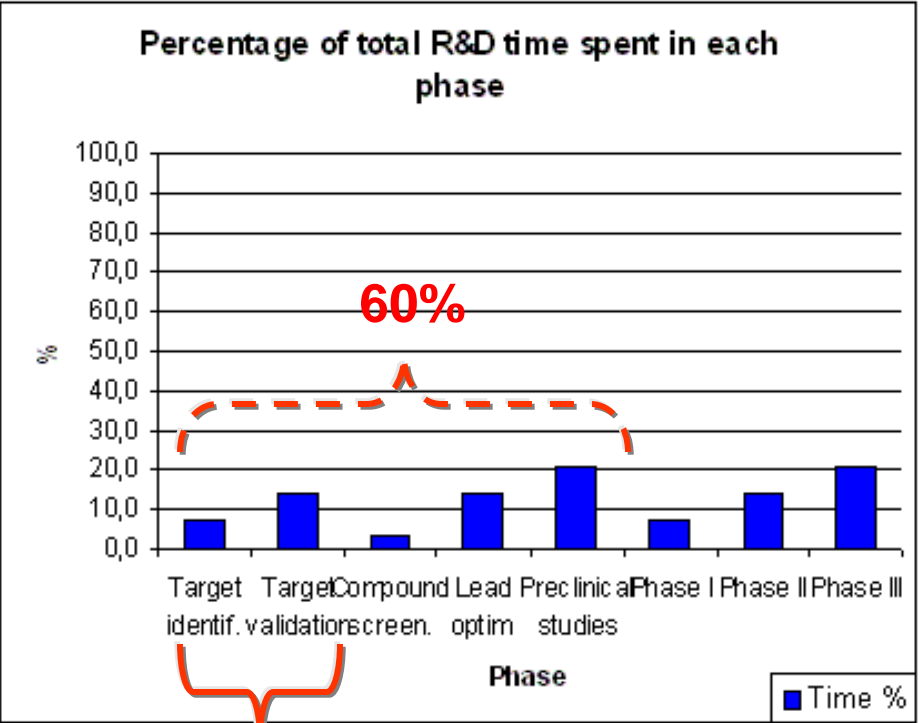
# Biomarker discovery (target identification and validation) is associated with high cost and time

## Cost (Avg 1billion)



40%

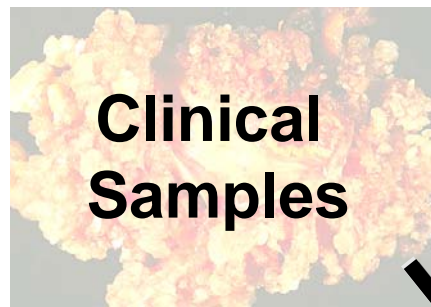
## Time (Avg 12yr)



20%

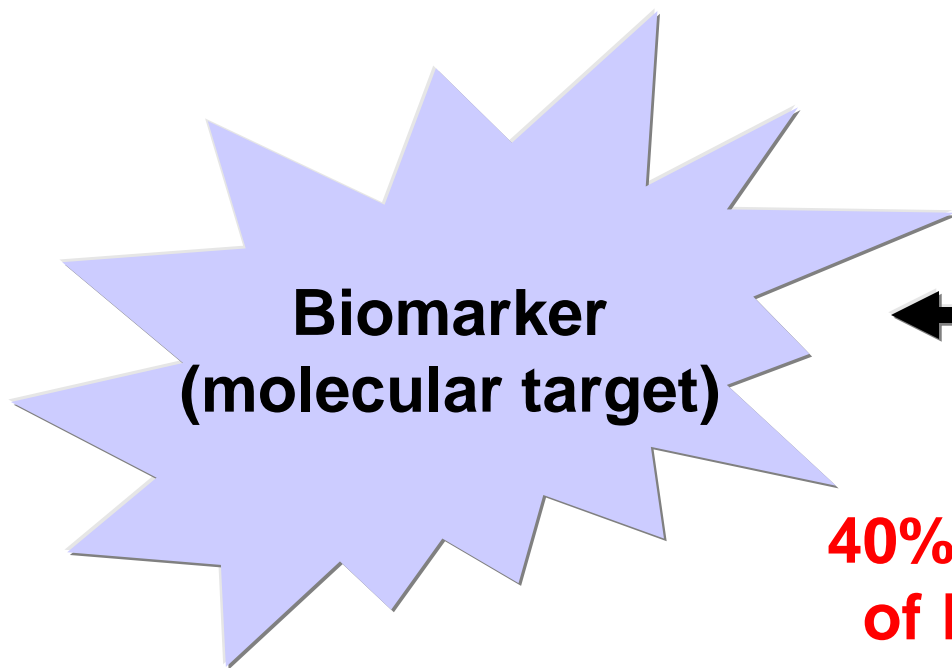
Source: Life Science Insights, Ernst & Young, Tufts CSDD and Boston Consulting Group, July 2004.

# Much of biomarker discovery efforts were focused on lab benches for the past 15 years

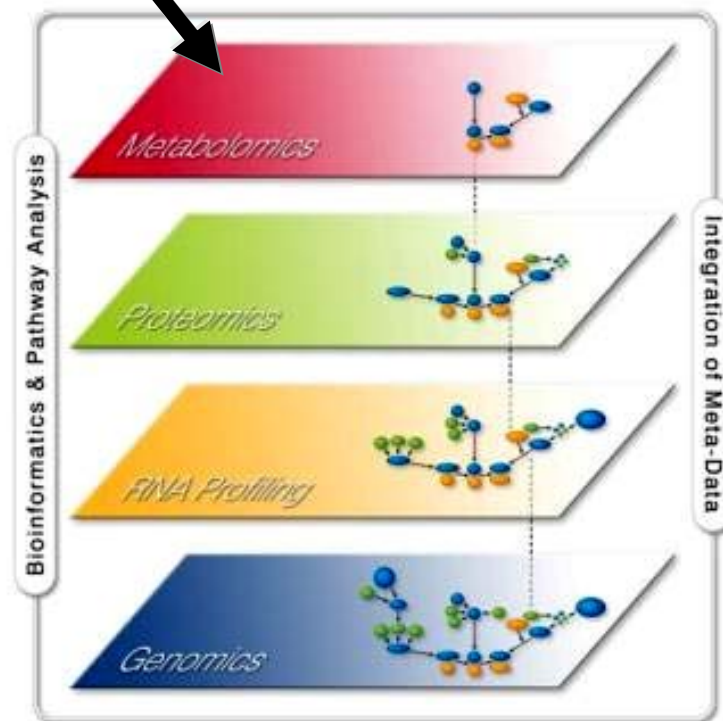


Samples land on lab bench

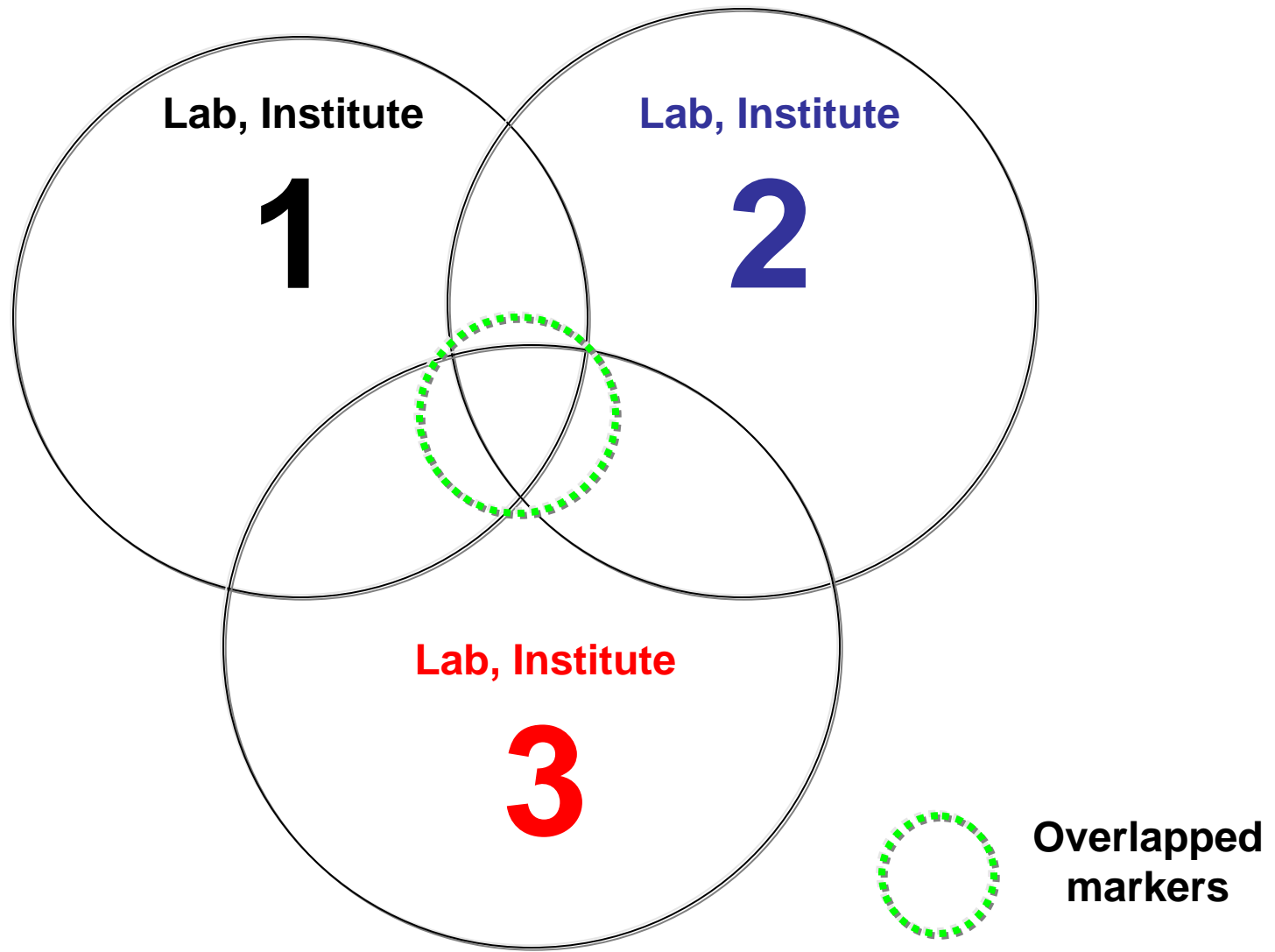
Sample "Procurement" neglected



**40% Cost of R&D**



# A small number of tumor biomarkers overlap between laboratories and institutes



**1. Too much capital, time and efforts spent on lab benches with bad samples.**

### **Mixture of samples**

$$\begin{array}{ccccc} \mathbf{100} & \mathbf{(perfect)} & \mathbf{X} & \mathbf{0} & \mathbf{(junk)} & \mathbf{=} & \mathbf{0} & \mathbf{(product)} \\ \text{(Score)} & & & \text{(Score)} & & & \text{(getting close to)} & \end{array}$$

**2. Biomarker discoveries begin with procurement of high quality clinical biospecimens.**

# Hackensack University Medical Center (120 yrs old)

1. Voted best in NJ and top 50 hospitals in US
  - a. 900 bed (Main campus) + 300 bed (North campus)
  - b. Ranks 4<sup>th</sup> in US for patient volume
  - c. Larger than most NCI-designated cancer centers
  - d. Approximately 150 clinical trials active
  - e. Ranks 5<sup>th</sup> in US for cancer patient volume (>60,000/yr)
    - (i) Out of >35,000/yr surgical procedures, about 1/2 is cancer related
    - (ii) Currently, the Tissue Bank procures <2% of blood and <0.5% of tissues

## **Multiple departments are involved in the Tumor Bank tissue procurement workflow**

### **DEPARTMENTS**

- A. In- and Out-patient Clinic**
- B. Laboratories/ Phlebotomy**
- C. Couriers**
- D. Surgical Procedure Rooms**
- E. Pathology Department**
- F. IT and Telecommunication department**
- G. Tissue Repository**

### **PEOPLE**

- Research, Education and Charge Nurses
- Schedule, Research and Data Coordinators
- Receptionist and Assistants ..etc



# Challenges and Solutions in Tissue Procurement Workflow

## PROBLEMS

1. Sample loss ( -\$500) due to lack of communication & information
2. Quality of biomaterials compromised due to lack of coordination
3. Disruption of routine workflows in Operating Rooms, Special Procedures and Pathology due to unexpected arrival of patients or samples without consent forms
4. IT- and Tele-communication not frequently accessible due to high patient volume and short staff

## Solution

Informatics-guided workflow, automate communications and a designated coordinators are used to help the procurement workflow

## SOLUTIONS

- 1. Communication and information** are facilitated by informatic software (LabMatrix) and IT automation in **real time**.
- 2. Key events are electronically tracked** by web-based software in real time through a centralized data management.
- 3. Digitized informed consents** and relevant legal documents are **always accessible** by RASi in **real time** via hospital network.
- 4. Designated clinical data coordinators** follows through the whole workflow point-by-point.

# Research nurses and coordinators initiate bioinformatics-guided tissue procurement process (\*Lymphoma Division)

Labmatrix - Mozilla Firefox

File Edit View History Bookmarks Tools Help

Sub... Con... Communica... Biomat... Genot... Sto... Custom ... Wor... Q... Log Off Imports Admin Help

TMBK\_Workflow Data Workspace

### Custom Data - TMBK\_Workflow

Subject:  Drop Subject here

Consent_Nurse_Name: <input type="text" value="Florence Nightingale"/>	Consent_Date: <input type="text" value="9/12/2007"/>	
Diagnosis: <input type="text" value="Leukemia"/>	Leukemic_Phase: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
WBC: <input type="text" value="100"/>	ANC: <input type="text" value="200"/>	ALC: <input type="text" value="300"/>
RBC: <input type="text" value="400"/>	Hemoglobin: <input type="text" value="500"/>	PLT: <input type="text" value="600"/>
Consented_Peripheral_Blood: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Blood_Drawn_Today: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Scheduled_Blood_Draw_Date: <input type="text" value="9/20/2007"/>
Consented_Tissue: <input type="text" value="Excisional Biopsy"/>	Consented_Tissue_Other: <input type="text"/>	
Scheduled_Surgery_Date: <input type="text" value="9/28/2007"/>	Surgeon_Name: <input type="text"/>	
IgG: <input type="text" value="700"/>	IgA: <input type="text" value="800"/>	IgM: <input type="text" value="900"/>
LD: <input type="text" value="1000"/>	Hep_B_Core_Antibody: <input type="text" value="Negative"/>	Hep_B_Surface_Antigen: <input type="text" value="Negative"/>
Hep_B_Surface_Antibody: <input type="text" value="Negative"/>	Hep_C: <input type="text" value="TBD"/>	Beta2: <input type="text" value="1100"/>
HIV: <input type="text" value="TBD"/>	CMV_Serology: <input type="text" value="Positive"/>	CMV_DNA: <input type="text" value="1200"/>
EBV_Serology: <input type="text" value="Negative"/>	EBV_DNA: <input type="text"/>	Immunofixation: <input type="text"/>

# Automated emails and paging procedures alert members of the tissue procurement “TEAM” in real-time

it_Documents	Subject	This Custom Data form d...	+ ...	...	...	...
Blood_Status	Subject	-	+ ...	...	...	...
_Consent	Subject	-	+ ...	...	...	...
_Special_Proc_B...	Subject	Only fill out this form whe...	+ ...	...	...	...
_Workflow	Subject	-	+ ...	...	...	...

und

Print
 Refresh

**BK\_Workflow**

	PHI	Req'd	Datatype
	<input type="checkbox"/>	<input type="checkbox"/>	Decimal
ral_Bloo	<input type="checkbox"/>	<input type="checkbox"/>	Yes/No
	<input type="checkbox"/>	<input type="checkbox"/>	List
Other	<input type="checkbox"/>	<input type="checkbox"/>	Small Text
_Date	<input type="checkbox"/>	<input type="checkbox"/>	Date
y	<input type="checkbox"/>	<input type="checkbox"/>	Yes/No
raw_Dal	<input type="checkbox"/>	<input type="checkbox"/>	Date
	<input type="checkbox"/>	<input type="checkbox"/>	Decimal
	<input type="checkbox"/>	<input type="checkbox"/>	Decimal
	<input type="checkbox"/>	<input type="checkbox"/>	Decimal
	<input type="checkbox"/>	<input type="checkbox"/>	Decimal
ody	<input type="checkbox"/>	<input type="checkbox"/>	List
finen	<input type="checkbox"/>	<input type="checkbox"/>	...

https://labmatrix.net - Notification - Mozilla Firefox

Operator: Match

Value: .+

Email Title: Notification from Labmatrix

Email Message:
 

The patient %subject% has been scheduled for surgery on this date %newValue%.  
 The patient's consent form has been electronically recorded in Labmatrix, under the %subject%'s patient record.  
 Please be sure to note this date on your schedule. Thank you.

Recipients:
 

- pathology@humed.com,
- operating\_room@humed.com,
- tissue\_bank@humed.com

Done labmatrix.net

# All digitized data associated with clinical samples are stored and documented (Biospecimen management and tracking)

The screenshot displays a web-based interface for biospecimen management. The main window shows details for a "2 DCIS biopsy" sample, including its name, type, access group, source subject, and storage location. A barcode is highlighted with a red circle. An inset window shows a "Storage Browser" for "rack/clinical specimens 1", listing various biopsy samples (1-A to 1-I) and their quantities. Another inset window shows a grid of sample slots (A-I, 1-9) with icons indicating the presence of samples. A QR code is shown below the main window, and a bottom inset window displays a series of histological images.

**Tissue Sample - 2 DCIS biopsy**

**Name:** DCIS biopsy  
**Type:** breast  
**Access Group(s):** BC  
**Source Subject(s):** BC.1 Roosevelt, Ms. Eleanor (NIH1)  
**Source Biomaterial(s):**  
**Suggested Discard Date:**  
**Created By:**  
**Received From:** Jeffreys, Patrick Dr. 10/3/2005  
**Sample Quality:** Apparent Quality-Acceptable  
**Anatomy/Cell Type:**  
**Current Status:** In inventory - stored  
**Storage Location:** rack/clinical specimens 1/1-A  
**Current Status Date:** 11/10/2006  
**Barcode:** 000021231545-00-3-329277  
**System Generated Barcode:** AA7289E7-CC74-43E8-B572-A72D7C2EA0C

**Storage Browser**

Location: rack/clinical specimens 1

Container	Contents
clinical...imens 1	
Row 1	
1-A	2 DCIS biopsy
1-B	4 IBC biopsy
1-C	17 DCIS biopsy
1-D	24 IBC biopsy
1-E	25 IBC biopsy
1-F	26 IBC biopsy
1-G	27 IBC biopsy
1-H	28 IBC biopsy
1-I	29 IBC biopsy
Row 2	
Row 3	
Row 4	
Row 5	
Row 6	
Row 7	
Row 8	
Row 9	

**rack/clinical specimens 1**

(Mouse over slots to see contents)

	A	B	C	D	E	F	G	H	I
1	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐
2	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐
3	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐
4	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐
5	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐	🌐
6									
7									
8									
9									

**2 DCIS biopsy**

**Tissue Sample - 2 DCIS biopsy**

General | Tissue Sample | Lineage | Custom Data | Workflows | Genotypes | Usage History | References | Attachments | Comments

# A combination of patient education and consent procedures are accomplished in digitized formats

New TMBK\_Consent Data      Workspace

**Custom Data - TMBK\_Consent**

**Consent**

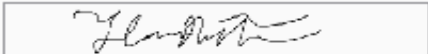

-I have read, or it has been explained to me, and I understand the information in this consent form. All my questions have been answered to my satisfaction. I consent to participate in this study.

-I understand that I will receive a signed and dated copy of this consent form for my records.

-By signing this consent form, I have not waived any of the legal rights, which I otherwise would have as a participant in a research study.

Florence Nightingale

Person obtaining consent



   9/21/2007  ▼

Signature of person obtaining consent      Date

Drop Subject here

Demo.1 Doe, John ()

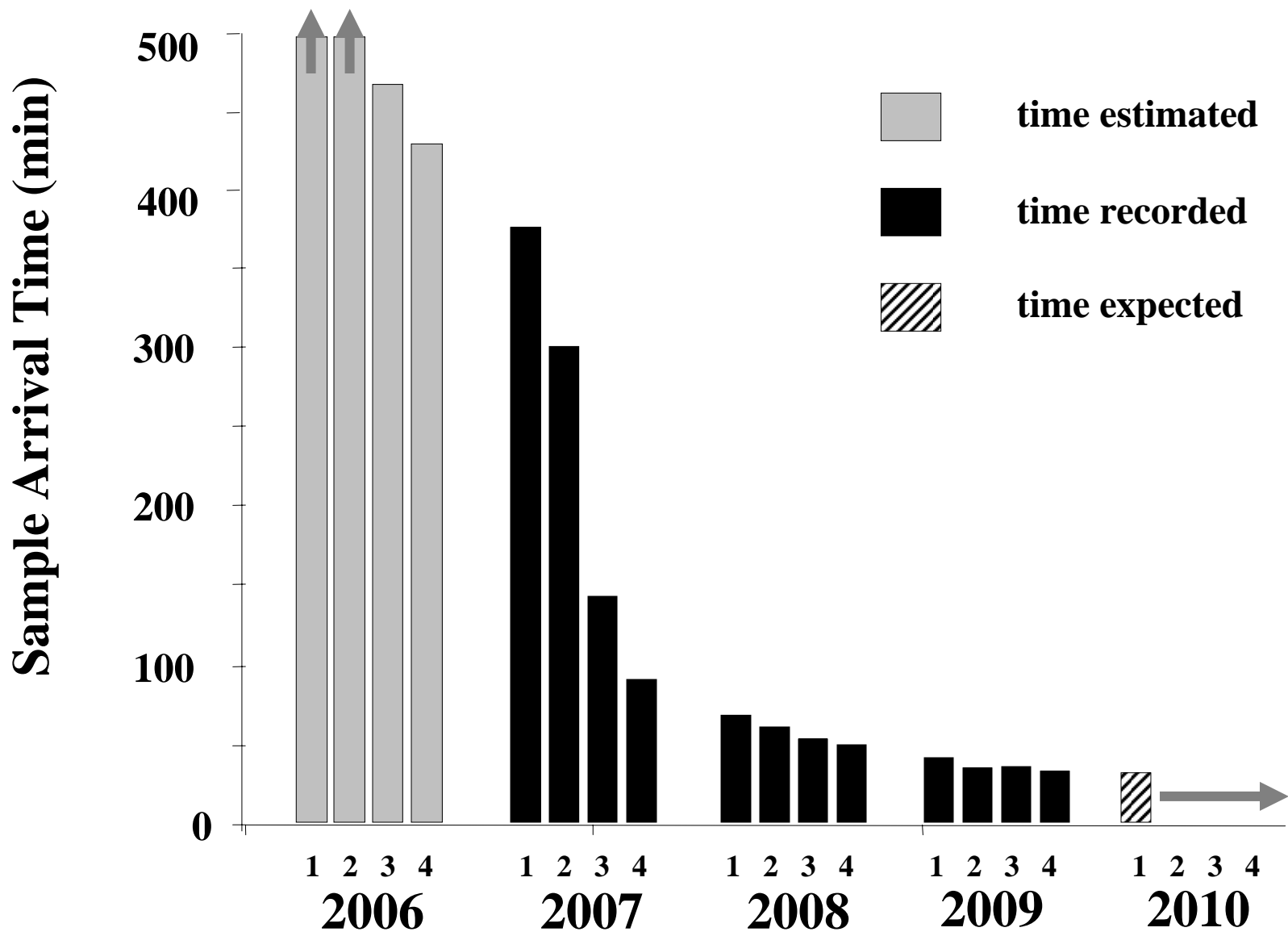
Subject

   9/21/2007  ▼

Signature of Subject or Signature of Legally Authorized Representative      Date

**A witness is someone who has no connection with the clinical trial. A witness is only required in cases where the subject cannot read or is not able to understand the consent document. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to and apparently understood by the subject or the subjects legally acceptable representative and that the informed consent was freely given by the subject or the subjects acceptable representative. In cases where this does not apply N/A should be placed in the witness section.**

# Improved workflow: Blood samples arrive within 40min





**From >60,000 cancer patients/yr, the Tissue Bank procures <2% of blood and <0.5% of tissues**

**Biggest Challenge: Increase the Number of Consents**

**The Problem = **Misconceptions****

- a. Don't want to be the guinea pig
- b. Don't want surgeons to take out extra tissue
- c. Afraid of not getting the best treatment when not agreeing to consent, so patients sign consent forms but donating only blood and not tissue
- d. Afraid that pathologist will not have enough tissue to diagnose
- e. Don't want personal identification/information released to public
- f. Afraid that insurance companies will request research information



## Entry Point of Informed Consent: **Success Rate**

- **10%:** Nurse or coordinator calls patient and consent for the first time – no prior knowledge of tissue banking
- **50%:** Nurse or coordinator calls patient after educating the patient about Tissue Banking during hospital visit and consent at later date
- **80%:** Educating and consenting patients in pre-admit setting as patient is already signing important documents (15min)
- **85%:** Nurse or coordinator educate and consent within the outpatient clinic (15min)
- **75%:** Patient is educated and consented by physicians at initial office consultation (5min)
- **90%:** Patient is educated and consented by nurse or coordinator pre-surgery (>20min).

# Challenges of Obtaining Informed Consent at HUMC

- ❖ **Physicians, nurses and staff are too busy to consent due to workload**
- ❖ **Physicians do not want disruptions in everyday workflow**
- ❖ **Physicians in various clinical settings do not have research nurses who can consent – lack of manpower**

**Conclusion: Unlikely to get help from the clinical side**

**Solution: Educate patients and general public**

- ❖ **Need user friendly information brochures and interactive medium**
- ❖ **Need to educate IRB from non-academic medical centers**

**Regional medical center like HUMC needs help from OBBR and biospecimen research network**

# Summary

- **Informatics and automation are used to guide the procurement workflow to maximize communications between interdepartmental personnel.**
- **In real time and web-based software are used to increase efficiency of the data management during the procurement process.**
- **Patient/general public, clinicians and IRB must be educated to significantly improve tissue banking**
- **User friendly (7-8 grade reading level) tissue banking brochures and interactive medium in multiple languages are required for an effective informed consent process**

# Acknowledgment

1. **Andrew Pecora (Chairman, Director of the Cancer Center)**
2. **Andre Goy (Chief of Lymphoma, Deputy Director of the Cancer Center)**
3. **Liz Koller (Admin Director, Cancer Center)**
4. **Jonathan Walland (Director, Clinical Research)**
5. **Tissue Bank Staff**  
**Clinical: Russ Haystrand, Tania Zielonka, Peggy Ford**  
**Scientific: Yvonne Remache, Ushma Jag, Jordan Lu, Angelica Castro, Raj Gharbaran, Sang Park, Hiren Patel, Cooper Walland**
6. **>8 Couriers**
7. **>20 Phlebotomists**
8. **>6 schedulers in OR procedures**
9. **>10 OR nurses, educators, charge nurses**
10. **>10 Radiation Oncology staff (Core and FNA biopsies)**
11. **>5 Surgeons currently actively participating (Dr. Dan Smith)**
12. **>20 Research nurses**
13. **>40 Research Data and Clinical Data Coordinators**
14. **>4 Preadmission staff**