OBBR Office of Biorepositories and Biospecimen Research



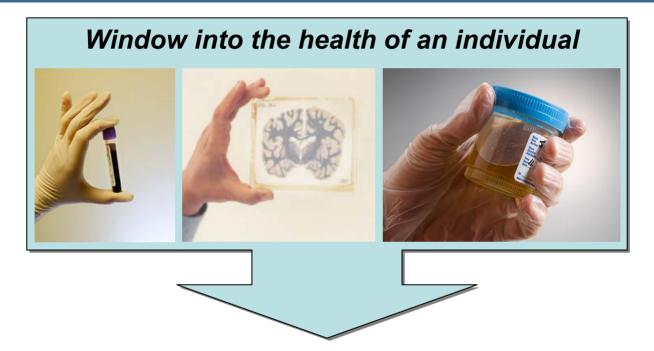
Mark David Lim, Ph.D.

AAAS Science and Technology Policy Fellow National Cancer Institute



The *biospecimen* - The *personalized* part of personalized medicine

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Identify targets for drug development, treatment and prevention
Identify biologic variations that determine drug efficacy and drug toxicity
Define markers for susceptibility, screening and reoccurrence
Validate new therapeutics and diagnostics

Molecular Research and Analyte Variation

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Biospecimen is still reacting to stresses during its collection, processing, and storage

How can we tell biologic fact from biologic artifact?

Pitfalls for translational research using human specimens:

- Varying methods of collection, processing, and storage can alter the physical/biologic state of the specimen
- Varying associated specimen data elements alter what the scientist knows about the character/nature of the specimen
- Variable clinical information alters what the scientist knows about the patient (biologic context of the specimen)
- Variable restrictions (patient consent; other ethical, legal, and policy issues) alter what the scientist may do with the specimen and/or data

Blood is a complex biospecimen

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- Travels through all tissues in the body
 - 60,000 miles of vessels
 - Important for tumor growth and metastasis
- Readily collected in the clinic

Numerous Roles:

- delivery of nutrients
- removal of metabolites
- delivery of oxygen
- removal of carbon dioxide
- immune response
- response to injury

• etc...

Complex Composition:

Biologically active!

- red blood cells
- white blood cells
- platelets
- almost every protein
- genomic transcripts
- etc...

Blood Collection and Processing Variables

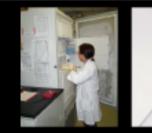
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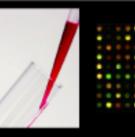


Patient Preparation and Blood Collection



Blood Processing and Storage





Translational Research

Blood Collection and Processing Variables

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Patient Preparation and Blood Collection

Patient Health, Hydration, Diet

Medications

Patient Position

Tourniquet time duration

Gauge of needle

Order of draw

Type of tube, additives

Blood Collection and Processing Variables

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Blood Processing and Storage







Translational Research

Serum vs plasma vs whole blood

Processing Procedure

Processing Temperature

Centrifuge Speed

Centrifuge Temperature

Storage Temperature

Freeze-thaw

Tissue Biospecimens

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Variables (examples):

- Antibiotics
- Other drugs
- Type of anesthesia
- Duration of anesthesia

Time 0

Arterial clamp time

Variables (examples):

- Time at room temperature
- Temperature of room
- Type of fixative
- Time in fixative
- Rate of freezing
- Size of aliquots



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The Biospecimen Research Network (BRN)



Biospecimen Research Database

Search Results

2 Study(s) Found Modify Search Page 1 of 1

Rai Alex J, Gelfand Craig A, Haywood Bruce C, Warunek David J, Yi Jizu, Schuchard Mark D, Mehigh Richard J, Cockrill Steven L, Scott Graham BI, Tammen Harald, Schulz-Knappe Peter, Speicher David W, Vitzthum Frank, Haab Brian B, Siest Gerard, Chan Daniel W

Specimen: Fluid /Plasma /Frozen / None /

Platforms: Protein - 1D/2D gels / Protein - Mass Spec /

The presence of protease inhibitor (PI) cocktail appears to perturb the native profiles of several proteins, particularly higher abundance proteins including apolipoprotein A1, apolipoprotein A2, haotoolobin (albha and beta subunits). transthvretin and fibrinogen - as defined by in-gel trvotic *Proteomics* ,2005 ,<u>Vol. 5</u> ,Page 3262

Pub Med

Rai Alex J, Gelfand Craig A, Haywood Bruce C, Warunek David J, Yi Jizu, Schuchard Mark D, Mehigh Richard J, Cockrill Steven L, Scott Graham BI, Tammen Harald, Schulz-Knappe Peter, Speicher David W, Vitzthum Frank, Haab Brian B, Siest Gerard, Chan Daniel W

Specimen: Fluid /Plasma /Frozen / None /

Platforms: Protein - Mass Spec /

HUPO plasma samples show significant differences compared to reference plasma collected according to BioVisioN sample protocols, perhaps due to investigation of different protocols for EDTA/citrate specimen collection in this studv- a maior finding is the detection of platelet-derived *Proteomics* ,2005, Vol. 5, Page 3262

Pub Med



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The Biospecimen Research Network (BRN)



Advancing Cancer Research Through Biospecimen Science

- Biospecimen Research Database
- Annual BRN Symposium

http://www.brnsymposium.com

March 2008 Symposium

Pat Brown MD PhD (Stanford) Pitfalls and Gaps in Research Using Human Biospecimens

> **Steve Gutman MD (US FDA/OIVD)** FDA and Biospecimens: Going for the Gold

Scott Patterson PhD (Amgen) Signal:Noise? The Importance of the Pre-Analytical Phase in Sample Storage

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http://www.brnsymposium.com

2009 Symposium

March 16-19, 2009 Bethesda North Marriott Hotel & Conference Center Bethesda, Maryland

> Two days of scientific talks One day of interactive workshops *Registration open soon*

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<u>Research</u>

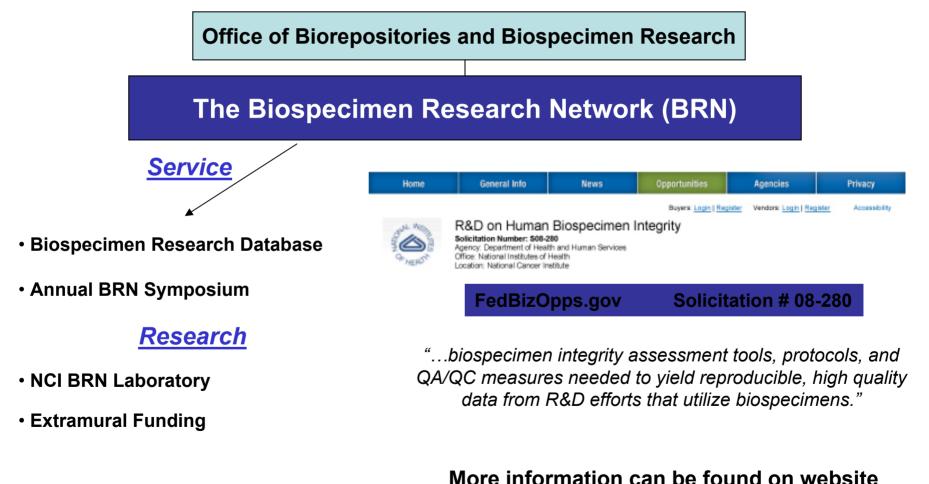
- NCI BRN Laboratory
- Extramural Funding



Innovations in Cancer Sample Preparation

"...sample collection, processing, isolation, storage, purification, preservation, and, in the case of stored tissues, reversal of adverse events resulting from storage and preservation."

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Deadline extended until December 9, 2008 (2pm)

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The Biospecimen Research Network (BRN)



- Biospecimen Research Database
- Annual BRN Symposium

Research

- NCI BRN Laboratory
- Extramural Funding

More opportunities to be announced

http://biospecimens.cancer.gov

E-mail <u>biospecimens@mail.nih.gov</u> to be added to our listserv

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The Biospecimen Research Network (BRN)



- Biospecimen Research Database
- Annual BRN Symposium

Research

- NCI BRN Laboratory
- Extramural Funding

Collaboration

- Working Groups and Workshops
- Training new biospecimen scientists



2008 Experimental Design Workshop Publication in preparation

Center to Reduce Cancer Health Disparities

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More information?

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