



Chain of Trust

Development of a Common Biospecimen Coordination System and Informatics Infrastructure for NCI Prostate SPOREs

RFP No. N02-CO-51018-17

Julie A. Schneider
Technology Program Manager
Office of the Director, NCI
April 13, 2005

Jeff Thomas
Senior Advisor
Technology Transfer Branch, NCI

Acknowledgements

NCI Organ Systems Branch

- Jorge Gomez and Andrew Hruszkewycz

NCI Center for Bioinformatics

- Ken Buetow and Sue Dubman

NCI Research Contracts Branch

- Robin Irving
- Todd Cole

NCI Technology Transfer Branch

- Jeff Thomas
- Tom Stackhouse



Chain of Trust

Biorepositories for Molecular Medicine and the National Biospecimen Network Concept

Data Are Becoming Available on an Unprecedented Scale

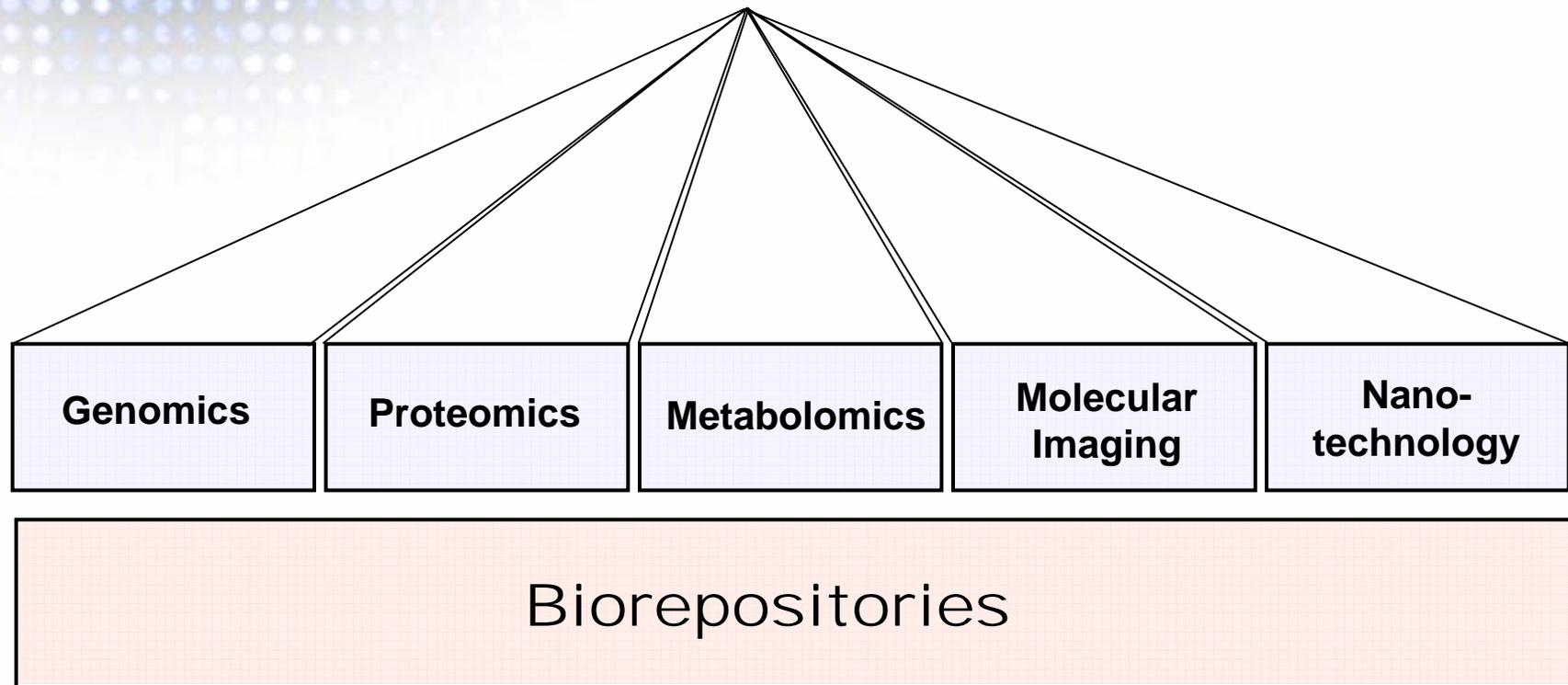
*Molecular
Data*

*Clinical
Data*



Advances in information technology enable large, multi-institutional studies

Biorepositories Support Discovery in Molecular Medicine



Biorepositories in the United States

- More than 300 million specimens are stored from >150 million cases, and over 20 million new specimens are collected each year (Source: *Handbook of Human Tissue Sources*, RAND 1999)

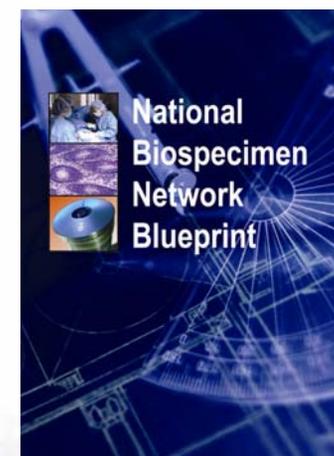
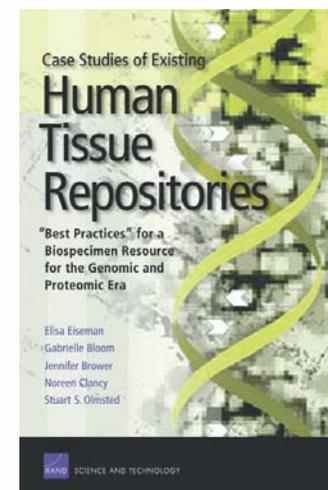
Current Challenges Regarding U.S. Biospecimen Access and Usage

- Scarce and variable clinical data
- Variable biospecimen collection methods
- Laborious exchange of information
- Varying approaches to patient consent and privacy protections



NBN Concept Developed with Extensive Input from the Cancer Community

- RAND Report on Case Studies of Existing Biorepositories: “Best Practices” for a Biospecimen Resource in the Genomic and Proteomic Era (<http://www.rand.org/publications/MG/MG120>)
- National Biospecimen Network Blueprint (http://www.ndoc.org/about_ndc/reports)



Key Requirements for a New Biorepository System

- Diversity of cancer types and populations based on continual review of researcher needs
- Access through a timely, centralized peer-review process
- Ethical and privacy compliance through a chain of trust
- Resources provided without intellectual property restrictions
- Best practices-based SOPs to enable reproducible and comparable results
- Pathology and clinical annotation (including longitudinal)
- State-of-the-art informatics system to streamline the research production process and create *in silico* research capability
- Communication and outreach efforts



Chain of Trust

Prostate SPORE NBN Pilot Project Background

NCI's Specialized Programs of Research Excellence (SPOREs)

- Program established in 1992
- Currently 58 SPOREs focusing on 14 organ sites
- Funded by P50 grants
- Conduct interdisciplinary, translational research
- Each SPORE program is overseen by a Principal Investigator (PI)
- Each SPORE program has an existing tissue bank
- For more information, see <http://spores.nci.nih.gov/>

Prostate SPORE Programs and Principal Investigators

Program	Principal Investigator
Baylor College of Medicine	Timothy Thompson, Ph.D.
Dana-Farber/Harvard	Philip Kantoff, M.D.*
Johns Hopkins University	William Nelson, M.D., Ph.D.
Mayo Clinic	Donald Tindall, Ph.D.
MD Anderson Cancer Center	Christopher Logothetis, M.D.
Memorial Sloan-Kettering Cancer Center	Peter Scardino, M.D.*
Northwestern University	Chung Lee, Ph.D.
University of California, Los Angeles	Jean deKernion, M.D.
University of California, San Francisco	Marc Shuman, M.D.
University of Michigan	Kenneth Pienta, M.D.
University of Washington / FHCRC	Paul Lang, M.D.

*Designated by Prostate SPORE PIs as primary points of contact for the NBN pilot

Goals for testing the NBN concept with the Inter-Prostate SPORE Biomarkers Study (IPBS)

- Determine the feasibility of establishing a biorepository network based on the NBN concept
 - Evaluate a controlled approach to biospecimen collection, processing, storage, and dissemination for a specific scientific study
- Pilot an infrastructure to annotate and integrate specimen banks to enhance the quality and availability of specimens and associated data for the broader scientific community

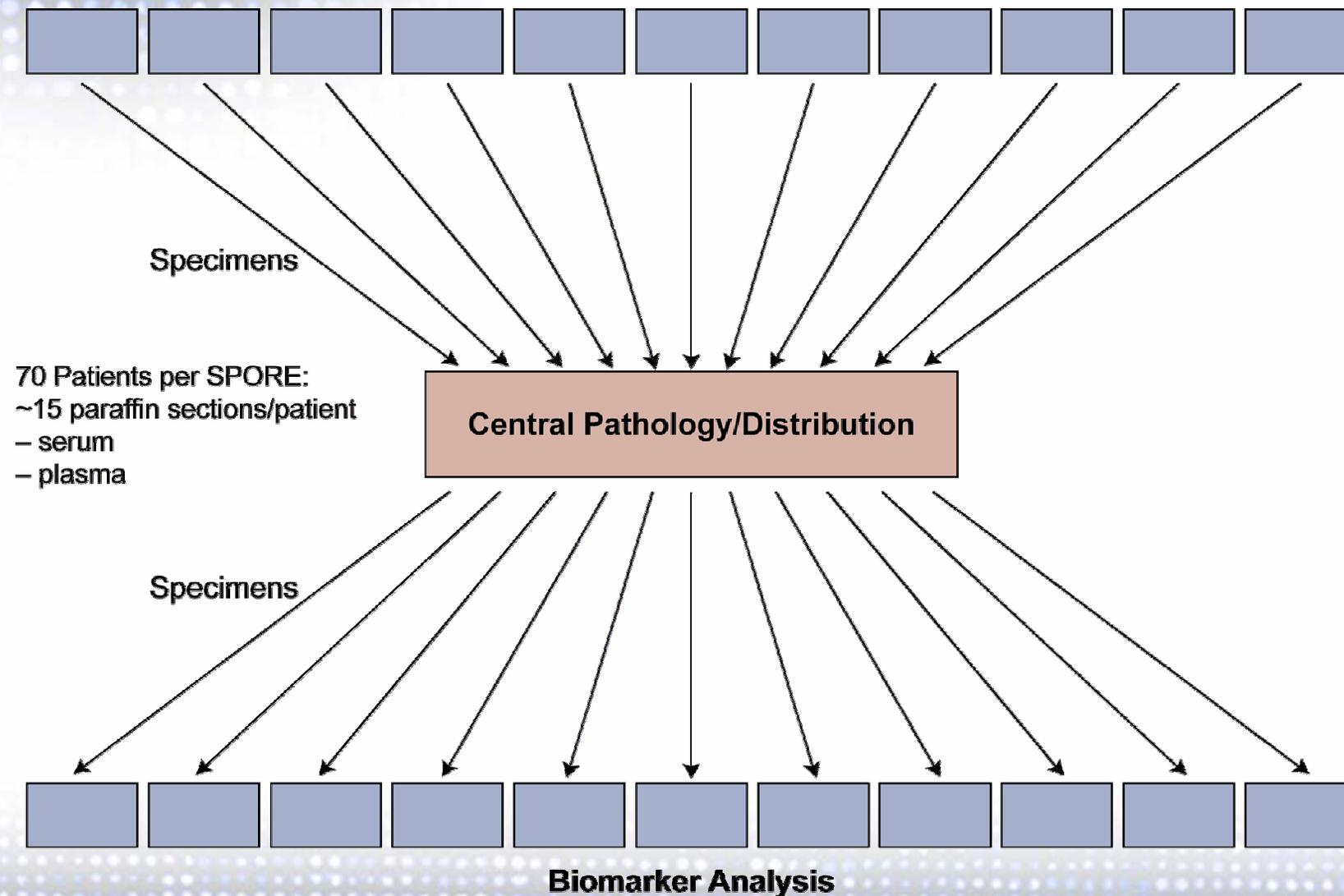
IPBS Goals

- Conduct a multi-institutional Inter-Prostate SPORE **prospective** validation study of five promising prognostic biomarkers selected by meta-analysis
- Conduct limited, focused **retrospective** studies of three promising biomarkers that require additional evidence of prognostic utility before conducting prospective validation studies
- Establish a resource of **well-characterized tissue and serum samples linked to clinical and epidemiological data** for future biomarker discovery and validation.

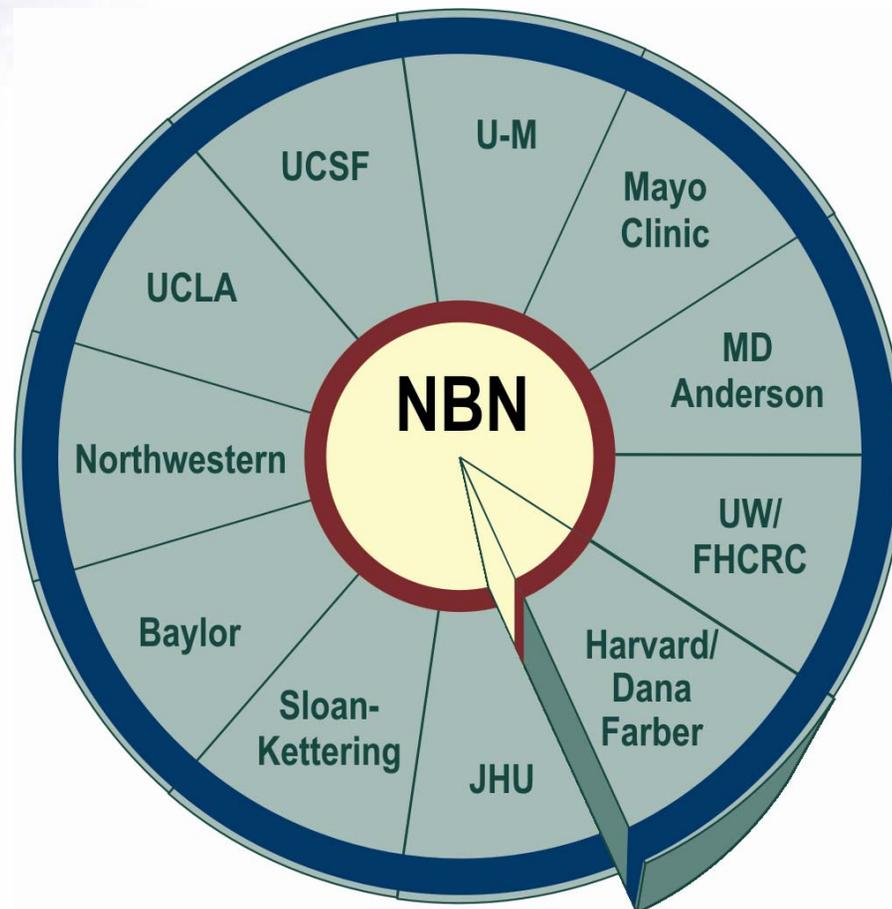
The IPBS: A Pilot Framework for the NBN Concept

- Collect **high-quality biospecimens with detailed annotation** suitable for biomarker validation studies
- Employ **standardized protocols** for biospecimen collection, annotation, processing, storage, and dissemination
- Create an **informatics infrastructure** that links multiple programs and allows communication and exchange of data and samples
- Develop **common policies and procedures** to govern prioritization and access to biospecimens stored in a common repository

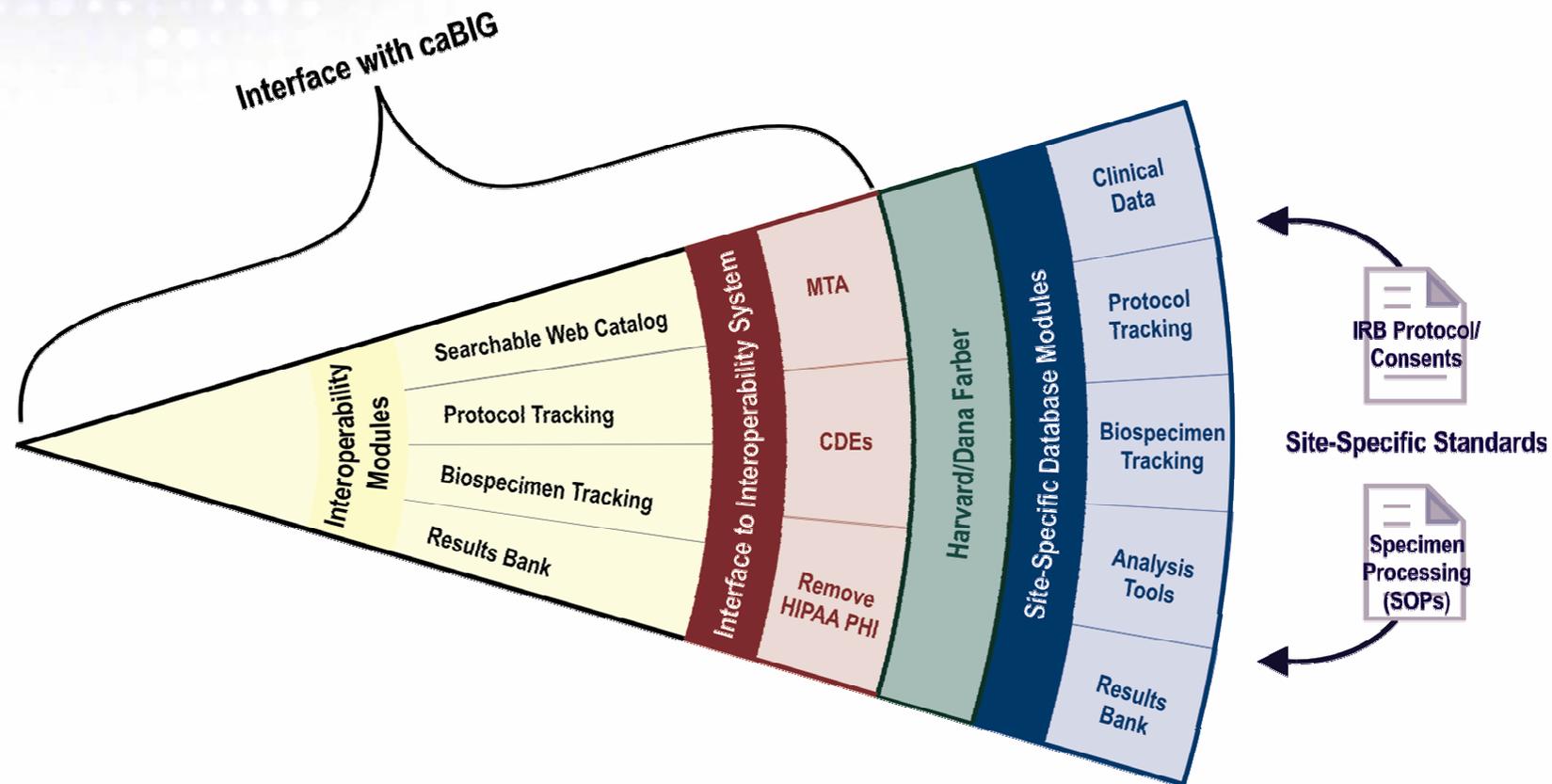
IPBS Model for Patient Enrollment and Sample Collection



Prostate SPORE NBN Pilot Informatics Vision



Prostate SPORE NBN Pilot Informatics Vision, continued



Prostate SPORE Task Force for NBN Implementation

Pathology/Tissue Processing

- Mark Rubin, Chair, Dana-Farber
- Larry True, FHCRC
- Timothy McDonnell, MD Anderson
- Gustavo Ayala, Baylor
- Angelo De Marzo, Johns Hopkins

Clinical and Epidemiology

- Paul Lang, Co-Chair, FHCRC
- James Montie, University of Michigan
- Alan Partin, Johns Hopkins
- Bruce Trock, Johns Hopkins

Laboratory Medicine

- George Klee, Mayo Clinic
- Herbert Fritsche, MD Anderson

Bioinformatics

- Paul Fearn, Memorial Sloan-Kettering
- Borko Javanovic, Northwestern

Regulatory Affairs

- Teri Mielese, UCSF

Additional Information about the Prostate SPORE NBN Pilot Project

- prostateNBNpilot.nci.nih.gov



Chain of Trust



RFP Overview

Overall RFP Objective

- Identify a Contractor to develop a Biorepository Coordination System and Informatics Infrastructure for the Prostate SPORC programs to:
 - Create an interoperable informatics system that leverages caBIG tools wherever possible
 - Develop a harmonized approach for biospecimen collection, processing, storage, and distribution
 - Coordinate the processing and storage of biospecimens for the IPBS
 - Establish a common informed consent process and material transfer agreements

Phased RFP Approach

Phase	Description	Duration
1	<ul style="list-style-type: none">• Develop detailed design plan for Phase 2• Present two viable alternatives	3 months
2	<ul style="list-style-type: none">• Implement Common Biospecimen Coordination System and Informatics Infrastructure in 11 Prostate SPOREs	20 months

Major System Components

- Human subjects protection, informed consent process, and privacy protection
- Standardized procedures for biospecimen collection, processing, annotation, storage, and dissemination
- Quality assurance and quality control
- Integration with associated clinical data, both retrospectively and prospectively
- Informatics system requirements and standards
- Biospecimen and data access policies
- Biohazard considerations and packing, shipping, and storage policies
- Intellectual property and ongoing system maintenance
- Establishing a common repository of biospecimens unused by the IPBS
- Personnel management

Human Subjects Protection, Informed Consent Process, and Privacy Protection

- Contractor shall not interface directly with patients
- Contractor shall not use the biospecimens and data collected for research purposes, nor distribute these resources without authorization
- Contractor shall assist the Prostate SPOREs in developing a harmonized approach for addressing human subjects and privacy issues

Standardized Procedures for Biospecimen Collection, Processing, Annotation, Storage, and Dissemination

- Develop (in collaboration with the Task Force) a set of common, best practices-based procedures for collecting, processing, annotating, storing, and distributing biospecimens
- Maintain detailed annotation about biospecimens collected, particularly in situations where complete standardization is not possible
- Address multiple biospecimen collection variables

Quality Assurance and Quality Control

- Establish a process to verify and validate the quality of biospecimens collected to ensure that they are suitable for high throughput analyses of the genome, transcriptome, and/or proteome

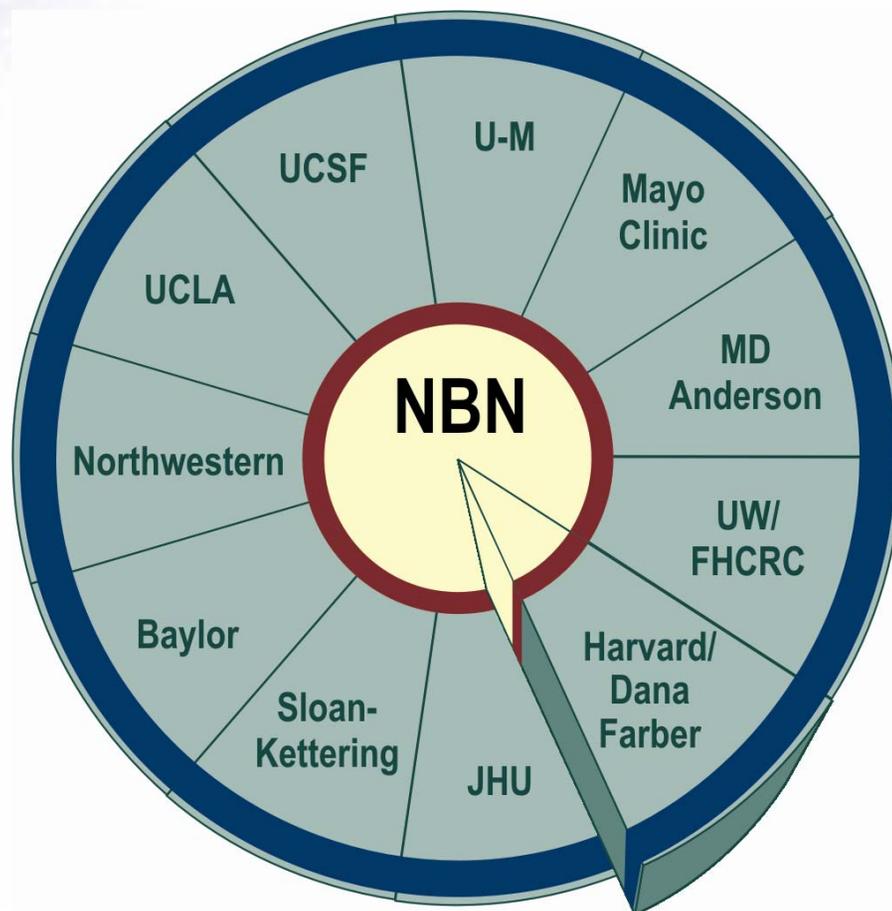
Integration with Associated Clinical Data

- Assist the Prostate SPORes in collecting and managing clinical data relevant to the IPBS study

Selected Informatics System Requirements and Standards

- Develop an interoperability system to allow data and specimen sharing among Prostate SPORE programs
 - Interoperability system must be caBIG compatible at the “sliver” level by time of pilot system delivery
 - Utilize caBIG tools wherever possible (e.g. caTISSUE, caTIES)
- Assist Prostate SPOREs in connecting site-specific databases to the interoperability system
 - Does not include upgrades or modifications to existing Prostate SPORE databases
- Submit all CDEs used in the interoperability system to the EVS and caDSR
- Develop a modular, scalable system that can extend to additional sites and different cancer types

Prostate SPORE NBN Pilot Informatics Vision



Biospecimen and Data Access Policies

- Contractor will be expected to participate in meetings of the Governance Board, which will oversee biospecimen prioritization and access policies
- First priority for biospecimens collected under this contract is for the IPBS
- Biospecimens unused by the IPBS will be allocated to researchers based on merit-based, peer review of scientific proposals
- Proposals will be reviewed by the Biospecimen Utilization Subcommittee, a subcommittee of the project Governance Board

Biohazard Considerations and Packing, Shipping, and Storage Policies

- Train all personnel involved in handling biospecimens and relevant biosafety concerns and regulations
- Pack all biospecimens appropriately to ensure protection from temperature variations
- Comply with all Government specifications and regulations for shipping, handling, and transporting biospecimens
- Store all biospecimens according to best practices

Intellectual Property and Ongoing System Maintenance

- Comply with the deviated data rights clause included with the RFP
- Address relevant intellectual property issues in project management plan
- Address relevant issues in the data sharing plan

When Does NCI Utilize a DEC or FAR Clause Deviation?

- To more effectively carry out the NIH Mission to improve the Public Health.
- For example: making the tools of scientific discovery (e.g., research tools and data) available to the research community without IP constraints to further advance biomedical research.
- Examples of past Initiatives using a DEC and/or FAR clause deviation:
 - Full-length cDNA
 - Proteomics Technologies Research Resources
 - Initiative for Chemical Genetics

Types of Data Anticipated Under this Contract

- “Fundamental Data” is data first-produced by the contractor as defined in the Deviation to FAR Clause 52.227-14 Rights in Data-General (e.g., interoperability software, biospecimen characterization data). The Deviation applies to all such data.
- Other data first-produced by the contractor that is NOT Fundamental Data is covered by the standard FAR Clause 52.227-14 Rights in Data-General.
- Data Produced by Third-parties: The contractor has no rights in such data (e.g., SPORE Program data). Handling of third-party data will be pursuant to the terms of the contract.

Software not First-produced by the Contractor Under this Contract

- Examples:
 - Existing proprietary software
 - Software with third-party obligations
 - Incompatible Open Source software (e.g., under a GNU-type Public License)
- Incorporation of software not first-produced under this contract into a Deliverable requires the NCI Contracting Officer's permission.
- It is the Contractor's responsibility to assure that all Deliverables provide the Government with all applicable rights defined the FAR Clauses.

Project Management Plan - Intellectual Property

- Describe how research resources (e.g., biospecimens, software) will be managed and shared.
- Specifically address any reach-through rights for biospecimens and data collected.
- Demonstrate organizational infrastructure and staff experience with respect to IP and technology transfer

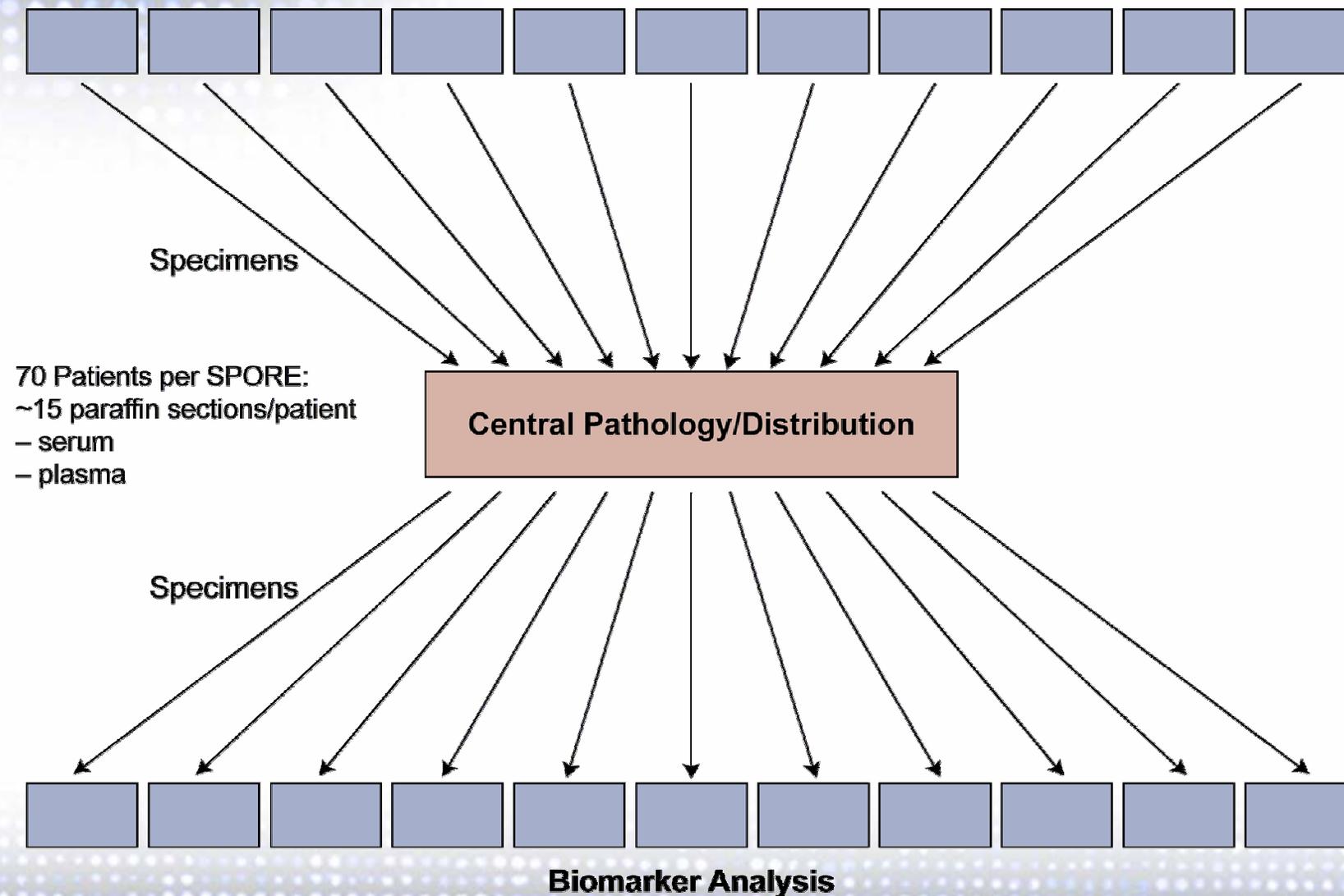
Data Sharing Plan

- The Plan should address how data will be shared with the research community (e.g., publication, website).
- Data Sharing Plans shall be consistent with the Deviated FAR Clause 52.227-14 Rights in Data-General
- Offerors in the competitive range will have an opportunity to clarify unacceptable Data Sharing Plans.
- Final Proposal Revisions with unacceptable Data Sharing Plans may not be considered further for award.

Establishing a Common Repository of Biospecimens Unused by the IPBS

- The Contractor will manage a common repository of biospecimens throughout the project
- This common repository will distribute specimens to the Prostate SPOREs for the IPBS
- The Contractor will work with the Task Force to determine the preferred location of this repository
- Access to biospecimens remaining in this repository that are unused by the IPBS will be governed by the Biospecimen Utilization Subcommittee

IPBS Model for Patient Enrollment and Sample Collection



Personnel Management

- The Contractor shall employ a comprehensive personnel management plan that addresses how to utilize existing personnel at the Prostate SPORE programs and other individuals working in affiliated institutions

Timeline and Next Steps

Event
RFP Released – March 31, 2005
Proposals Due - May 4, 2005
Technical Evaluation Panel
Negotiations Conducted
Source Selection Approved
Contract Award



Chain of Trust

Development of a Common Biospecimen Coordination System and Informatics Infrastructure for NCI Prostate SPOREs

RFP No. N02-CO-51018-17

Julie A. Schneider
Technology Program Manager
Office of the Director, NCI
April 13, 2005

Jeff Thomas
Senior Advisor
Technology Transfer Branch, NCI
April 13, 2005