



OBRR

Office of Biorepositories
and Biospecimen Research

Pathologists and Prospective Specimen Collection for Research

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The Promise of the Future

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Appropriate specimens from properly consented patients will provide the substrate to answer important scientific questions and provide data for future reflection and study



The Reality of the Present

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- **No standardized methods of prospective collection**
- **Research underway but not complete to understand important collection variables**
- **Pathology staffing inadequate for tissue collection**
- **No funding for collection efforts**
- **No standardized data base for collection parameters**



Early Efforts Failed

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- **At least two efforts to provide commercial infrastructure for tissue collection failed**
- **Pharma and Dx company initiatives are scattered and fragmented**
- **Local institutional and research efforts survive at the will of small group of investigators**



Operational Challenges

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- **Patient Protection**
- **Sample Quality**
- **Clinical Data Quality**
- **IT/Bioinformatics**
- **Logistics**



Patient Protection

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- **Legal & ethical requirements**
- **IRB process**
- **Consent process**
- **Permission process and monitoring**
- **HIPAA compliance**
- **De-identification of data**
- **Data and sample security and confidentiality**
- **Stewardship of samples and data**



Sample Quality

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- **Operational standardized process**
- **Equipment validation and monitoring**
- **Process and timing validation**
- **Pathologic verification of sample quality**
- **Sample Storage and Shipping**



Clinical Data Quality

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- **Standardized data collection format**
- **Standard process of data collection**
- **Validaton of process**
- **Monitoring of data quality**



IT/Bioinformatics

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- **Data capture**
- **Data integrity**
- **Data standardization**
- **Data transmission**
- **Query processes**
- **Query security**
- **Data transmission**



Logistics

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- **Personnel recruitment, training and competency assessment**
- **Supplies**
- **Bar coding**
- **Shipping**
- **Storage**
- **Infrastructure**
- **Inventory Control**



Pathologist Role

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Pathologists and laboratory staff in large facilities are well trained to handle all aspects of this process

- Many team activities in laboratories
- Must adhere to patient protection issues in clinical work
- Understand constraints of data and specimen quality
- Deal daily with IT bioinformatics challenges
- Commonly deal with similar logistics



Why are Pathologists Considered Peripheral?

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- **Not seen as team players with researchers**
- **Often naturally reticent**
- **Inadequate staffing....No time!**
- **Inadequate funding....No money!**
- **Process is designed without their input making it seem impractical to them**



Key Leverage Points

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- **Standardized protocols**
- **Standardized IT/bioinformatics**
- **Standardized principles**
- **Practical local implementation**
- **Funding opportunities**
- **Rewards for collaboration**
- **Peer pressure**



Recommendations of NQF*

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**Design work so that
it is easy to do it right
and hard to do it wrong**

***The National Forum For Health Care
Quality Measurement And Reporting**



Designed Standardization

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- **Uniform, simple protocols based on principles that are scientifically sound**
 - Consent
 - Consent tracking
 - Tissue acquisition standards
- **Job aids to make process understandable**
 - Videos
 - Posters
 - Kits
 - Standardized downloadable forms



Designed IT/Bioinformatics

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- **Easily implemented standards**
- **Web based deployment**
- **Uniform data field requirements**
- **Standardized bar coding and tracking software**
- **National standards, with flexible local deployment options**



Local Flexible Deployment Options

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- **More than one way to follow a principle**
- **Must provide standard training in principles**
- **Allows for personal imprinting of process**
- **Provides opportunity for improvement and learning**



Funding Options

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- **CMS codes for properly obtaining specimens**
 - Professional and technical components
- **Institutional incentives**
 - RFA's to act as local training sites
 - RFA's for developing processes, personnel curricula, IT solutions



Rewards for Collaboration

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- **Requirement to have dedicated pathology resource at each site**
- **Pathologist involvement in study design, analysis and publication**
- **Enhanced status of site if team involved in process**



Peer Pressure

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- **Recognition by NCI of sites/grants/programs which comply with standards**
 - "Good housekeeping seal of approval"
- **Recognition of standards by pathologists organizations like CAP**
- **Inspection, competency assessment and proficiency testing program with publication of results**



Summary

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- **Research is proceeding to develop principles of sample collection to enhance quality'**
- **Pathologist and lab staff are key players in process**
- **Careful design of all elements of process are needed before deployment to enhance acceptance.**
- **Incentives will be needed to assure success.**