

## Tissue Bank Challenges

Repository and Pathologist View  
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## 2 Types of Challenges

- Repository managers
- Pathologists who provide tissue to banks

## Repository Manager Challenges

- Confidentiality
- Tissue Accuracy
- Specimen Tracking
- Consent Tracking
- Specimen Disposition
- Which IRB?

## Confidentiality

- Limited access to identified information
- Confidentiality agreements
- Security of identified information
- Retention of identified information
- Tracking of disclosure of information

## Tissue Sample Accuracy

- Tissue samples and associated identifying information must be used to insure that samples received:
  - Represent tissue of study patient
  - Contain tissue of interest to the study
  - Do not contain artifacts which render tissue unusable for research

## Specimen Tracking

- Sample identification
- Sample storage and retrieval
- Tracking of samples to/ from investigators
- Tracking of samples back to institutions
- Tracking of sample disposal

### Consent Tracking

- Samples with/without consent
- Level of consent
- Patients deceased (with documentation)?
- Tracking of consent when samples used
- Sample reuse beyond study definition

### Specimen Disposition

- Sample tracking/ retrieval to insure prompt return of samples
- Sample disposition when block expended
- Sample disposition when study closed

### IRB Jurisdiction

- Which IRB has ethical oversight for the repository?
- Which IRB has ethical oversight when a study using tissue is approved by clinical trial group or other entity?

### Repository Approaches

- Tracking issues require data bases
- Identified information must be secured and disposition must be controlled by policy
- Data base security and access must be carefully controlled
- Local IRB coordinated approach to HBM issues must be arranged to insure uniform education about policies

### Pathologist Challenges

- Patient Care
- Patient Consent
- Cost
- Malpractice Risk
- Ownership/credit

### Patient Care

- Blocks may be needed for future clinical tests (Her2 in breast cancer)
- Retrospective review of samples when new risk factors found, new diagnoses considered
- Late requests for second opinions

### Patient Consent

- What documentation should be requested?
- How should consent information be recorded?
- Institutional policies are highly variable as are the wishes of IRB's.

### Issue of Cost

- Pathologists are busier with smaller staffs
- Block selection for tissue banking is time consuming (expensive)
  - Reports, blocks, and slides must be obtained
  - Report and slides must be reviewed
  - Block must be selected and shipped
  - Documentation must be maintained

### Issue of Malpractice Risk

- Retention of slides or blocks beyond the times mandated by regulatory agencies may be seen as promoting malpractice risk.
  - Can be used in litigation longer
  - Can be reviewed and diagnosis challenged
  - Policy must be specific and documented or patient can challenge removal of tissue from department which may promote litigation

### Issue of Ownership

- Pathologists view blocks are potential valuable resource for own research.
- Issues of ownership vary by state
- Ownership becomes bargaining issue

### Approaches to Patient Care Issues

- Uniform guidelines for tissue retention for patient care are needed that are not state specific and are widely endorsed and enforced by regulatory agencies such as CAP/JCAHO.
- Tissue requirements must be mindful of potential patient care needs (retention of unstained slides or availability of rapid return of materials when necessary)

### Patient Consent Approaches

- Uniform consent form should be provided or education about key elements
- Process to assure proper procedures are followed should be available and simple
- Documentation guidelines or forms should be created/provided (?web based)
- Information should be available to pathologists to enable understanding of process

### Approaches to Cost

- Mechanisms to provide payment and ease of submission/shipment of materials are needed.
- Uniformity of submission requirements would be helpful.
- Strategies for case identification are needed which are not disruptive to patient care

### Malpractice Risk Approaches

- Pathologists should be informed about the value of standardized procedures and documentation in preventing malpractice risk
- Policies should be developed for situations of discrepant diagnoses which mitigate against malpractice risk

### Approaches to Ownership Issues

- National guidelines are needed for determining ownership or establishing priority of granting tissue requests.
- Strategies for giving credit to pathologists for participation are needed which they accept.
- Access to tissue resources could be enabled for those providing tissue so that individual studies could be done.

### Public Education

- Public opinion could be marshaled to promote tissue acquisition by publicizing results of studies where cooperation led to important new treatment strategies.
- Patient advocacy groups and oncology groups could promote tissue banking using media and individual pathologist contact.

### Pathologist Cooperation

- Participation of all types of pathologists in creating solutions will promote cooperation.
- Involvement of pathology organizations as resources for information and guideline development will foster support.
- Communication about the impact of tissue banking on future cancer care will promote cooperation.