Methods repositories use to protect subjects

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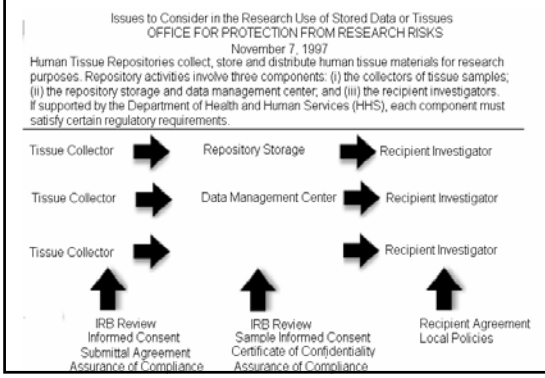
Methods to Protect Subjects

- Well defined operating policies; Mechanisms for governance and oversight
- Internal procedures to protect privacy/ confidentiality
- Investigator agreements
- Informed consent
- IRB review

OHRP Model



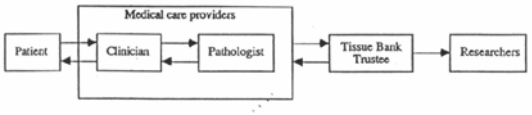
Operating Policies & Governance

- Governance and Oversight
  - Steering and/or oversight committees, ethics advisory boards
- Operating policies and procedures
  - Consent
  - Protecting privacy/confidentiality
  - Return of research results
    - if, when, under what conditions

Privacy/Confidentiality

- Anonymization of Specimens/data
- Coding of Specimens/data
  - Links maintained by repository but identifying information never released to investigators
- Encryption
- Limited access/secure storage

Privacy and confidentiality procedures: Honest Broker Model



Interposing a tissue bank trustee between patients and their caregivers and biomedical researchers enables strict control of information flows (arrows} associated with research using banked tissues.

Additional Protections

- Employee Confidentiality Agreements
- Certificates of Confidentiality
  - http://grants1.nih.gov/grants/policy/coc/
  - Protect identifiable research information from forced disclosure
  - Appropriate for genetic studies, including collecting and storing biological samples for future use
  - Must inform participant in consent
  - Covers all events after issuance
  - May not be useful for all repositories

Consent

- Common Rule Requirement
  - Exceptions
    - Unidentified, anonymous, de-linked
    - Linked with investigator use agreement
    - IRB waiver
  - Study specific
    - Most useful for defined studies
  - Consent for future use
    - Useful for repositories
    - Still useful post-HIPAA

Model Consent for Future Use

- NCI/NAPBC model consent
  - Committee
    - patient advocates, ethicists, lawyers, pathologists, clinicians, and laboratory researchers
  - Designed to meet 45 CFR 46 requirements
  - 27 focus groups
    - representing different socio-economic levels, racial and ethnic groups, genders, and professional and patient groups
  - Simplified and converted to low literacy level
  - Presented to a wide variety of forums
  - Tested at multiple sites (Sheila Taube, NCI)

Key Points

Advantages:

- Simple, understandable
- Tiered consent minimizes the psychosocial risk of re-contact for new consent
- Acceptability: Patients and advocacy groups, surgeons and physicians, NBAC, NCI Clinical Cooperative Groups
- Makes specimens available for research that might otherwise be discarded

Post-HIPAA

- Privacy Rule allows authorization
  - To collect data for a database or repository
  - Not for future research use
- Various options exist for use
  - Study specific authorization
    - Often not feasible
  - Waiver of authorization
  - De-identification
  - Limited dataset with data use agreement

IRB Review

- Review of operating policies and procedures
  - oversight
  - Process issues
    - Conditions for collection
    - What data will be captured/provided
    - Identifiability
    - Potential uses and risk evaluation
  - Protections
    - Privacy/confidentiality
    - Data security

Impact on research subjects

- Societal and individual benefits balanced against risks
- Much specimen research may be considered minimal risk
- Level of risk may be determined by probability and magnitude of harm

Websites

- Office of Human Research Protection
  - http://ohrp.osophs.dhhs.gov/
- NCI Resources Development Branch
  - http://www-cdp.ims.nci.nih.gov/rdb.html
- Bioethics Resources on the Web
  - http://www.nih.gov/sigs/bioethics
- National Bioethics Advisory Commission
  - http://www.bioethics.gov