Implementing Honest Broker System(s) in Academic Medical Centers: The Pittsburgh Experience

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The Researcher’s Dilemma: How can I study patient medical information when I’m not providing care to them?

• “Whatever I shall see or hear in the course of my dealings with patients...I will never divulge, holding such things to be holy secrets” Hippocratic Oath

• Before releasing medical records, HIPAA requires written authorization from the patient, where the authorization specifies how PHI will be used, and who will access it

• No authorization is needed when information is de-identified
The Clinical Institution’s Dilemma: How do we de-identify PHI and share these with ‘outside’ researchers

- Hospitals and their ‘affiliated’ Universities are usually legally separate entities
- Most large hospital systems have records and specimens stored in multiple places, with paper charts and multiple electronic MR systems
- May have little incentive to invest in an expensive infrastructure to support research, when their mission is patient care
Honest Broker

• “Someone who speaks to both sides involved in an argument or disagreement and tries to help them agree” Cambridge Dictionary

• Tissue/data bank trustee that “acts as a well defined barrier between the clinical environment (in which fully identified, confidential patient information is exchanged routinely as part of medical care) and the general research community (in which all information must be de-identified completely).” Dhir, 2008, Cancer 113:1705-1715
Honest Brokers as Trustees

- Individual(s) serving as HBs are not part of the research team
- Must be members of the clinical facility workforce (or Business Associate)
- Only entity that can link research data and clinical identifiers
- Retains code so that information can be updated over time; superior to anonymization
- Protects confidentiality of patient data and ensures honest research
UPMC *Certified* Honest Broker Systems

- More than 80 Honest Broker Systems at UPMC
- Set up for department/division/clinic/lab/bank
- Vary in size and design; may be intrinsic to, or embedded in, a repository IRB protocol
- Written to cover specific records, databases, samples
- Supports retrospective and prospective research
- Requires approval by Pitt IRB and by UPMC Privacy Officer
Establishing a Certified HB System

• Group or Department or Program identifies need and meets with designated IRB staff
  – Staff examines other alternatives / existing system; discourage establishment of new HB system
• Reviews need; types of info to be accessed and shared; who will serve as HBs; planned training and oversight; infrastructure / support
• ‘Application for Certification of Honest Broker Systems/Processes’ is submitted to IRB first
• Reviewed and approved by IRB, and then by UPMC Privacy Officer
Key Elements of Application (1)

- Identify individual responsible for oversight*
- Name all individuals performing HB services*
  - *Must be part of UPMC ‘workforce’
- Identify medical records systems to be accessed
  - other materials? (specimens; radiographic images)
- Address how materials will be de-identified to comply with HIPAA (Safe Harbor/Limited Data Sets)
  - How will system ensure that LDS are consistent with data elements described in IRB protocol?
Key Elements (2): Policies & Procedures

• Assigning linkage codes to de-identified info
• Managing codes to prevent researcher from accessing identifiers
• Ensuring IRB approval prior to release of info
• Documenting each HB transaction
• Routine monitoring of released data to ensure compliance with HIPAA de-identification rules
• Maintaining security of identifiable PHI by HB system
• ‘Certification of Honest Broker Responsibilities’
Institutional Oversight Challenges

• ‘Shared’ governance – Who takes responsibility?
• HB applications have not been integrated into IRB electronic review system
• Obtaining timely (annual?) updates of activities
• Absence of a formal ‘renewal’ process
• Lack of resources for efficient institutional monitoring of listed procedures via research compliance audits
• Limited training provided by IRB of HBs
• Variability in infrastructure and support
Investigator Use of HB System

• Investigators contact the honest broker in their department/division and request services
  – Informal call: to establish what materials are available
• Investigator prepares IRB protocol
• HB signs study-specific ‘Honest Broker Assurance Form’; uploaded into IRB application
• Investigator completes whatever application is required by the HB system to access records/specimens
By signing below, I agree / certify that:

1. I have reviewed this project with the Principal Investigator and agree to de-identify and, if applicable, to maintain linkage code information for data (including specimens) that will subsequently be accessed by the research team.

2. I will, under no circumstance, provide the PI or any member of the research team with information that would permit the identification of research subjects.

3. I will not intervene or interact with identified human subjects during the conduct of this research project.

4. I will maintain complete confidentiality of research subjects’ private information.

Title of Study: 
Principal Investigator: 

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Additional optional comments of Honest Broker: 

Name of Honest Broker System or Process: UPMC/IRB Honest Broker Approval Number: 

- Large collection of frozen specimens & paraffin blocks
- Includes excess clinical tissue and specimens collected with consent
- Can be linked to medical record information by honest brokers, and to other institutional research / clinical repositories
- Requests are reviewed by tissue utilization committee
Health Sciences Tissue Bank: HB 15

• Activities covered by HSTB IRB Protocol
  – Specimens stored in 4 hospitals, and off-site
  – IRB protocol describes operation of HB 15

• Supported by 6 Departments / Divisions
  – Pathology / HSTB
  – Cancer Registry (Registry Information Services)
  – Otolaryngology (Head/neck cancer)
  – Gynecologic Oncology
  – Oncology Informatics (Pathology)
  – Department of BioMedical Informatics

• Continuity of leadership
Tissue/Data/Chart review/Honest broker services Request Form

Please Remember:
1. Please complete entire form. All items must be answered – fill in N/A where applicable.
2. Upon receiving all paperwork, the tissue bank will send a confirmation email and a prospective date of completion.
3. Tissue/biological specimen/Data Acquisition: Please indicate all information to process the tissue including handling & acquisition of the tissue and biological specimens, time allotments (if applicable), packaging of the tissue, contact person for pick-up, etc. Include as much information as necessary to meet the requirements of your project. Please also indicate all the data elements required for the project.
4. Please allow 4-6 weeks to process your request. Depending on the availability and/or complexity of the request, some tissues may take longer to obtain or process.

Checklist for Required Materials needed Tissue Request:

Frozen or Paraffin Materials:
- □ Completed Tissue Request Form
- □ IRB submission (if other than HSTB #0506140)
- □ IRB Approval Letter (if other than HSTB #0506140)
- □ Biological Specimen User Agreement (a PDF signed copy must be emailed to biscegliama2@upmc.edu)

**Included as last page of request form**
Honest Broker A
Identifies T2DM cases

PT Name linked to code (HBA-12345) and sent to HB B

Provides T2DM info
Linked to code (HBA-12345)

Investigator

Request: Samples/Data from 200 Patients with T2DM and Prostate CA

Honest Broker B
Obtains info on Prostate CA

Provides Prostate CA
Linked only by code (HBA-12345)
CARe: Center for Assistance in Research Using eRecord

- Medical Record HB System (HB 98) supported through UPMC and the Pitt CTSI (Regulatory Core)
Challenges with this System

• Patient IDs are not consistent across different clinical systems, affecting ability to merge data
• Investigators often start with 1 data source and then find other sources are needed. Requires re-identification of initial set – can be cumbersome
• Investigators often start with 1 set of variables and then desire additional; if data have been subsequently archived, may be difficult to retrieve
• Most HBs have clinical responsibilities which trump research requests
• Investigators must pay for report writers & programmers time
Honest Broker Systems Are Everywhere!

- Medical School, University of Michigan: HBO
- University of Arkansas for Medical Sciences – Translational Research Institute Honest Broker
- University of Florida: Privacy Office – HB System
- National Jewish Health Research Database and Biobank
- Children’s Hospital of Philadelphia Center for Biomedical Informatics
- U. Chicago Human Imaging Research Office
Getting Started...

• Dhir et al., A multidisciplinary approach to honest broker services for tissue banks and clinical data, *Cancer* 2008; 113:1705-15

• Boyd et al., The University of Michigan Honest Broker, *J Am Med Inform Assoc* 2009; 16:784-791

• Gupta et al., Evaluation of a deidentification (De-ID) software engine to share pathology reports and clinical documents for research, *Am J Clin Pathol* 2004; 121:176-186

Questions?