Overview

• Regulatory Concerns
• Consent Issues
• Use of Samples
• VA Policy Overview
• Proposed Changes
• The Emory IRB will review proposals involving human tissue, blood, genetic material and data to determine if it constitutes Human Subjects Research.

• Determination will be made as to whether research is subject to HHS Regulations.
  – State laws and institutional policies also apply.

• Key issues:
  – Obtaining specimens
  – Identifiability of specimens
• Consider the funding source
  – Federal: DHHS, HIPAA, & Emory
  – Industry/None: HIPAA & Emory

What rules apply?
• Identifiable: specimen can be linked, by an investigator, to an individual directly or indirectly through coding systems

• HIPAA cites 18 sources of protected health information (PHI) which can be identifiers
  – **PHI**: Name, address, telephone, fax, email, MRN, SSN, finger/voice prints, photos, device serial numbers, etc.
  – **NOT PHI**: Dx, age under 89, first 3 digits of zip code, pt outcome, type of device, etc.
Prospective collection of samples for future research requires consent from subjects.

- **Standalone**: Consent form for an independent project aimed at collecting samples for a repository.

- **Twinned**: Consent form (or addendum) for an existing research project to collect samples for future uses.

- **Pre-Planned**: Consent form (or addendum) for an existing research project to collect samples for a known future use.

Consent for Obtaining & Storing Samples
• HIPAA authorization is independent of consent
• Triggered by obtaining or disclosing PHI by a “covered entity” under the HIPAA Privacy Rule
• Kris West, JD: Emory Privacy Officer
  – Advises IRB/Investigators as needed
• IRB is the Emory Privacy Board

HIPAA Considerations
A place for the subject to indicate that s/he has provided his/her voluntary consent to the storage and genetic testing of the samples (i.e. consent).
  – Ideally, this should be set apart from any main consent.

A statement as to whether or not there will be identifying information on the stored samples.

A statement that the samples may be used for possible future research, including the area(s) of research for which they will be used, if known.

Required Consent Information
• Not related to participation in any other study
• No expectation of shared profit
• Who else will have access to samples, if known
• Whether the subject may be re-contacted by researchers
• How to request sample destruction (if date not specified)
Tissue obtained solely for research

Tissue originally collected for clinical care

Tissue Bank with Identifiable Tissue

1. Consent/HIPAA Authorization
2. Specific HIPAA Authorization
3. Data Use Agreement
4. Statement of Agreement
5. Not Human Subjects Research

Adapted from P. O’Rourke, PRIM&R Human Tissue/Specimen Banking Working Group

Process Flow & Requirements
Researchers must obtain HIPAA authorization for use of identified samples from a repository.

• Consent forms may allow for future use of identified samples but,

• No “Blanket HIPAA” for unspecified future research

Using Identified Samples
De-Identified Samples

Provided TO the repository without identifiers

- Identifiers scrubbed before banking
- Once de-identified, no longer “human subjects”

Provided BY the repository without identifiers

- Identifiers scrubbed before sample released
- Limited data set requires a Data Use Agreement
- Coded specimens require a statement of agreement
• Limited data sets can include some PHI
  – Admission, discharge, and service dates
  – DOB and/or DOD
  – Age over 89
  – 5-digit zip code or other geographic info above the street address level

• Data Use agreements
  – Set conditions for use of specimen
  – Limits who may receive/use the specimen
  – Requires recipient to not try to further identify specimen or contact donor

Limited Data Sets & Data Use Agreements
• Any code that may be used to uniquely identify the sample (but not the donor)

• Use of samples requires key to the code not be shared with recipient
  – “Statement of Agreement”

Coded Specimens
• VA-affiliated specimens must be kept in a VA-approved repository

• All research at the VA must be approved by the RDC

• Research protocols that plan to bank specimens should include a detail plan on collection, processing, and disposition of the specimens.

VA Overview
The Process


Open Comment period Comments reviewed → Open Comment period Comments reviewed

Proposed Changes
Proposed Changes

• Continuing review for minimal risk (i.e. expedited) studies may be either:
  – No longer required
  – Or given extended periods of approval

• Exempt Research further exempted from IRB review

• Apply DHHS rules to all HSR

• More protection against Informational Risk
  – All biospecimens may be consider “identifiable”
• Changes might require upfront written consent for all future research on specimens/data
  – Currently, research on existing specimens may be done without consent by stripping identifiers
  – Proposed changes would create need for an open-ended consent for any future use of specimen
  – Grandfather clause for existing specimens

Proposed Changes
• Comments are currently closed

• View comments on Regulations.gov
  – Keyword HHS-OPHS-2011-0005

• Read the changes at the DHHS website (hhs.gov)
Applicable regulations:

- 45 CFR §46
- 45 CFR §46.101(b)(4)
- 45 CFR §46.110(f)
- 45 CFR §46.116
- Public Health Service Act §301(d), 42 U.S.C. §241(d)
- VHA Handbook 1200.5: Requirements for the Protection of Human Subjects Research

Applicable Regulations for P&P’s
Thank you!