Tissue Banks: IRB perspectives

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Educating Investigators

• Focus, define, justify the project.
• Clarify control of samples and oversight mechanisms (pt/community rep?)
• Provide operating policies and procedures.
• Define who has access.
• Encourage grandfathering and honesty.

Nuts and Bolts - 1

• Personal vs. institutional collections.
• Defined vs. unlimited uses.
• Anonymous vs. coded samples.
• "Snapshot" of medical information vs. ongoing review of records or access to records (subjects should understand)
• Internal vs. external distribution.
• Academic vs. commercial collaborators.

Nuts and Bolts - 2

• Collaborative vs. non-collaborative.
• Provided gratis or sold.
• MTA with institution vs. letter of agreement with a PI.
• Who evaluates appropriateness of sample uses w.r.t. consent, scope, etc.
– Suggest bank, with IRB consultation prn

Consent vs. Authorization

• Authorization must be for specific uses
• HIPAA does not allow authorization for unspecified future uses.
• Almost insurmountable quandary.
– Try to be as specific as possible, give examples.
– Limit where reasonably limited.
– "Teaching" comparison.

Consent processes - 1

• "Up front" is our preference.
• Some groups think after a procedure may be better (?).
– Storage issues?
– Disingenuous?
• What if people decline: can you still use their tissues as excess clinical materials studies, after they've formally said "NO?"
Consent process - 2

• WHO's going to do it?
  • Physicians only willing for personal research interests, collections.
  • Institutional? Dedicated RN's?
  • Referral from physician: info/video?

Re-consent generally an awkward concept and not one easily implemented.

Consent FORM

• How much detail is needed/desired?
  • How much can we ask people to trust our judgement?
  • What level of detail about review process?
  • What kind of re-contact, if any?
  • Is it acceptable to simply ask to SAVE without specifying any further?