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Perspectives From Those Who Regulate Tissue Banks: The Moderator's Perspective

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Movement and Regulation of Tissue for Multiple Purposes by Multiple Parties

Who	What
IRB	Informed Consent
OHRP	HIPAA Pathways
OCR	Anatomical Gift Acts
FDA	Ownership Rights
State Law	
IP Laws	
IRB	Creation may be a Protocol
OHRP	HIPAA
OCR	-Registration
FDA	-Good Tissue Practice
	-Suitability
	-Safety
State Law	Licensure (some states)
Accreditation Bodies (AATB)	Limits on Commercial Use of Tissue
	Case Law

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Big Picture

- Human Biological Materials - defined by Source, Context, Use & Destination (NB: it may be hard to predict the future - you may end up *over-* or *under-* regulating yourself)
- Process by which specimens are obtained from Human Subjects
- Tissue Repository Practices and Rules
- Transfer of Specimens to Central Repositories
- Process to Access Repositories

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What are we talking about?

- Raw materials obtained from and/or used for treatment, research, product manufacture, and validation of diagnostics including:
 - cadavers
 - vacularized organs
 - blood and blood components
 - tumor and other tissues
 - ova and sperm/embryos
 - corneas
 - breast milk
 - bone
 - bone marrow
 - ligaments, skin, dura matter
 - heart valves
 - hair
 - DNA
 - fetal tissue

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Multiplicity of Regulation - Yet No Common Platform

- Requirements for procurement and subsequent rights to use are subject to varying laws and institutional policies depending on the type of biological materials involved, the circumstances of procurement, the parties involved and the ultimate use of the materials
 - There is no overall federal legislation detailing who has what rights to what materials. State or federal statutory provisions may apply in some circumstances. Case law is developing in litigation between various parties in interest.
 - As the value of biological materials and information derived therefrom continues to be developed and be recognized one can expect more disputes.
 - Many disputes involve difficult ethical as well as factual situations resulting in difficult to anticipate outcomes.

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Situational Regulation of Tissue Banking

- Federal Common Rule Human Research Protections
 - If tissue banking is done for research by Institution with Assurance: OHRP
- FDA Human Research Protections
 - If tissue banking is done for research purposes by an institution subject to FDA because institution will make submissions to FDA or research involves products subject to FDA approval
- Federal Privacy Protections under HIPAA
 - If PHI is disclosed by a Covered Entity, e.g., Academic Medical Center
- "Comprehensive FDA System" (Registration, Good Tissue Practices and Donor Suitability Regulations)
 - If tissue banking is done for purposes of human transplantation
- State Law
 - Buying/Selling tissue, privacy and other laws

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A few words about HIPAA. . .

- o February, 2004 Guidance and Q & A: Research Repositories, Databases and the HIPAA Privacy Rule
- o Tissue Samples themselves are not PHI (yet), but use of associated identifying information implicates Privacy Rule
- o Creation of Repository itself requires IRB/Privacy Board involvement; Probably a Protocol unto itself
- o Harvesting and Depositing Requires a HIPAA Pathway
 - 164.512(h) - Disclosures for cadaveric organ, eye or tissue donation and transplantation -- too narrow; Need the other pathways
- o Accessing tissue samples requires a "Second" HIPAA Pathway
 - Because, likely that "First HIPAA Pathway" for deposit wasn't specific enough
- o Don't forget about the Common Rule and IRB's ongoing involvement

The Regulators

- | | |
|------------------------------|--|
| o Julie Kaneshiro, MA | Policy Team Leader,
Office for Human Research
Protections |
| o Sally Hojvat, Ph.D, MSc. | Director, Microbiology Division
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| o Elizabeth L. Hohmann, M.D. | Chair and Director,
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