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Biobanking Basics: An Overview of Current Legal and Compliance Issues Related to Human Specimens Collected in Research

Monday, May 6, 9:30 - 10:45 AM

Instructors

Presented by
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AGENDA

- Ownership of Biological Specimens
- Informed Consent in a Nutshell
- A Peek at Federal Privacy Law
- State Law (Informed Consent, Privacy and Ownership)
- New Developments: ARRA/HITECH and GINA

Determining Ownership

Multiple Stakeholders with "ownership" interests in biological samples:

- Research Facilities/Academic Medical Centers
- Physicians/Scientists/Researchers
- Patients
- Pharmaceutical and Biotech Companies

What does it mean to "own" Biological Samples?

- What are the appropriate uses for donated biological samples?
- Can donors prohibit the unauthorized use or commercialization of their biological samples?
- Once biological samples are donated should a donor be allowed to direct what happened to the materials?
- What remedies should the law provide donors in cases of unauthorized use?
- Do tissue samples belong to the facility that maintains the repository, the researcher who collected the tissue, or to the participants who donated the tissue?
- How do we reconcile differences among state laws and federal laws in how these issues are addressed?

Biological Sample Ownership: Legal Precedent

Developments in Case Law

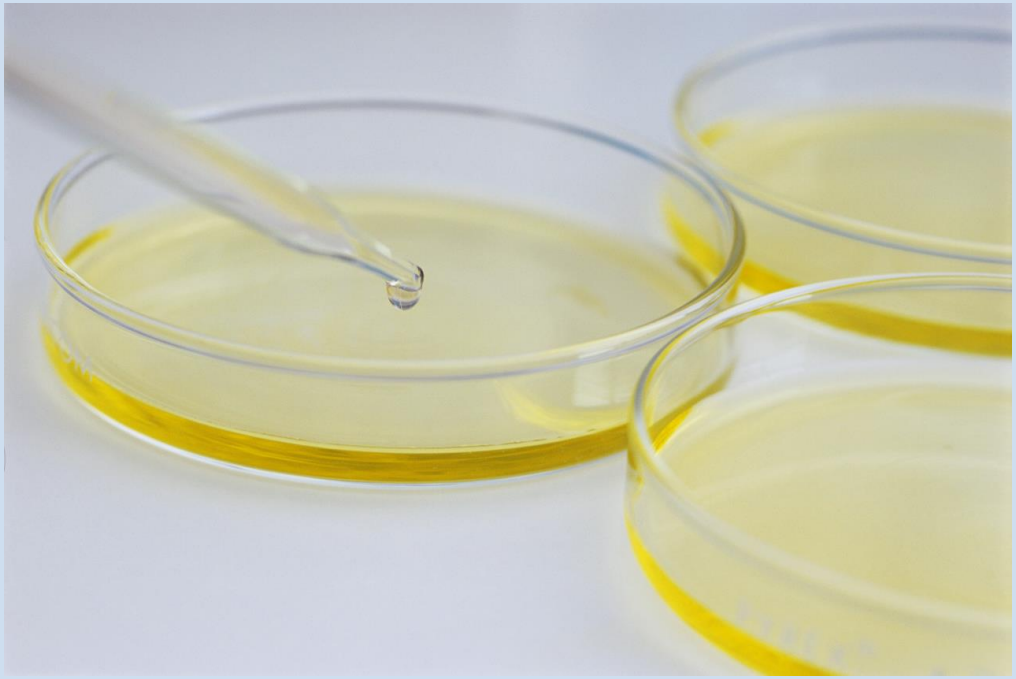
- Three major cases since the 1990s in the development of ownership rights in biological samples:
  - *Moore v. Regents of the University of California*
  - *Greenberg v. Miami Children's Hospital Research Institute, Inc.*
  - *Washington University v. Catalona*

Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990).

- Moore retained neither a possessory interest nor an ownership interest in his cells after they were removed. *See id*. at 487-89.
  - The threat of liability will have a chilling effect on research.
  - The patented cell line is distinct from the cells removed from Mr. Moore's body.

Unanswered Questions after *Moore. . .*

Would the Court's decision have differed if the researcher and the tissue donor were not in a doctor-patient relationship?



Greenberg v. Miami Children's Hospital Research Inst., Inc., 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

- No duty to disclose their economic interests in research to research subjects. *See Greenberg*, 264 F. Supp. 2d. at 1069-70.
  - Imposition of such a duty would have a chilling effect on medical research.
  - ***NOTE:*** The Court found that "in certain circumstances a medical researcher does have a duty of informed consent" with respect to other (non-economic) interests. *See id*. at 1070.
- Citing *Moore*, the Court concluded that the families had no possessory or ownership interest in their donated tissues. *See id*. at 1074-76.

Unanswered Questions after *Greenberg…*

- If the research subjects don't own their tissue samples, who does?

Washington Univ. v. Catalona, 437 F. Supp.2d 985 (E.D. Mo. 2006), *aff'd* 490 F.3d 667 (8th Cir. 2007).

- Dr. William Catalona was a respected urologic surgeon at Washington University.
- Dr. Catalona also conducted prostate cancer research as part of his employment.
  - Dr. Catalona collected blood and tissue samples from his surgical patients for use in research re: the genetic bases of prostate cancer.

Catalona, cont.

- Dr. Catalona helped to establish the Genito-Urinary (GU) Repository at Washington University to hold the collected samples.
  - The GU Repository also held samples collected by Dr. Catalona's colleagues.
  - GU Repository holds approximately 100,000 total samples, 3,500 of which were derived from Catalona's patients.

Catalona, cont.

- Patients contributing to the GU Repository executed informed consent forms.
  - Patients' contributions referred to as "donations".
  - Forms typically stated that the research subject could not claim "ownership rights" to any "resulting medical or scientific product."
  - Forms allowed the research subjects to withdraw consent and "discontinue participation."

Catalona, cont.

- In 2003, Dr. Catalona transferred to Northwestern University and sought to take the GU Repository samples with him.
  - Dr. Catalona sent each of his patients a form to sign allowing relocation of their samples and transferring the samples to him.
  - Approximately 6,000 patients signed and returned the form.
- Washington University filed a law suit to establish ownership.

Catalona, cont.

- The Court held that individuals who make an informed, voluntary decision to contribute their biological materials to a particular research institution for the purpose of medical research do not retain an ownership interest in those materials.
- Individuals cannot direct or authorize the transfer of their biological materials to a third party.
  - Under Missouri law, the Washington University exhibited ownership.
  - The contributions were *inter vivos* gifts to Washington University.
  - Pursuant to the informed consent forms, patients retained only the right to withdraw from the study and have their samples destroyed.

Practical Implications

- A researcher must disclose his/her financial interests in the research subject only if the researcher and the subject are in a doctor-patient relationship.
- A research subject does not retain any ownership interest in his/her tissue samples.
- Absent an agreement to the contrary, a research subject does not retain any right to the financial benefits arising from patents and commercialized products derived from his/her tissue samples.
- Language addressing disposition of tissue samples within informed consent forms, MTAs, and institutional policies help to document and inform the issue of ownership rights.

AGENDA

- Ownership of Biological Specimens
- **Informed Consent in a Nutshell**
  - **Department of Health and Human Services (HHS)**
  - **The Food and Drug Administration (FDA)**
  - **Differences between the requirements**
- Federal Privacy Law
- State Law (Informed Consent, Privacy and Ownership)
- New Developments: ARRA/HITECH and GINA

HHS Requirements: The Common Rule

- HHS Policy for the Protection of Human Subjects (45 CFR 46 Subpart A)
- **Human Research Protections in Canada**
  - http://www.circare.org/CAindex.htm

OHRP Policy & Guidance

- "*Issues to consider in the Research Use of Stored Data or Tissues*" (Nov. 7, 1997)
  - Identifies and clarifies issues for specimen collectors, IRBs and specimen recipients
    - Informed consent elements specific to collection for a repository
    - IRB oversight
    - Repository template ICF and Protocol
    - Submittal agreement
    - Recipient written usage agreement and assurance

http://www.hhs.gov/ohrp/policy/reposit.html

OHRP Policy & Guidance

- "*Guidance on Research Involving Coded Private Information or Biological Specimens*" (Oct. 16, 2008)
  - *Is research involving humans* when - private information or the specimens can be linked to the subject (directly or indirectly)
  - *Is **not** research involving humans* when:
    - Private information or specimens were not collected through an interaction with a living person for the proposed research, **and**
    - There are mechanisms to prevent the identity of the person becoming known

http://www.hhs.gov/ohrp/policy/cdebiol.html

HHS Enforcement

- OHRP authorized to oversee compliance and enforcement
  - Through federalwide assurance
  - No direct action against the investigator (compare to FDA)

FDA Informed Consent

- FDA elements of informed consent are essentially the same as the Common Rule, except:
  - ✓ FDA requires the confidentiality statement to include disclosure that the FDA may inspect the records." (21 CFR § 50.25(a)(5))
  - ✓ New ICF element to be codified at 21 CFR § 50.25(c)
    - "A description of this trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the Website will include a summary of the results. You can research this website at any time." (76 Fed. Reg. 2,256, 2,270 (Jan. 4, 2011))

FDA Guidance

- "*Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are not Individually Identifiable*" (April 25, 2006)
  - Outlines FDA enforcement discretion when certain human specimens are used for *in vitro* device investigations
  - Provides factors to determine whether the enforcement discretion will apply to specimens
  - Permits use of specimens without informed consent in certain, limited instances

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm

FDA Enforcement

- Regulatory compliance though a combination of surveillance, endorsement and education
  - FDA-regulated research monitored through on-site inspections and data audits
- Bioresearch Monitoring Program (BIMO)
  - Field investigators & FDA scientists
  - Several compliance programs
    - Good Laboratory Practices Program (non-clinical)
    - Clinical Investigator program
    - IRB Program

Points to Consider

- Know which regulations apply (may be both)
- Understand when informed consent is required and when it is not
- Ensure that the informed consent satisfies all required elements, as applicable and clearly addresses the use of specimens
- Understand enforcement authority and scope and the consequences for failure to comply

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- **Federal Privacy Law Overview**
  - **HIPAA**
- State Law (Informed Consent, Privacy and Ownership)
- New Developments: ARRA/HITECH and GINA

HIPAA

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
  - Administrative Simplification Provisions (Accountability)
    - Privacy
    - Security
    - Code Sets
  - Required the Secretary of HHS to adopt eight sets of regulations i.e., “Standards”
  - Plus Enforcement Rule
  - Plus Breach Nonfiction Rule (per the HITECH Act)

HIPAA Privacy Rule

- Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164 Subparts A and E)
  - Protected Health Information (PHI), including electronic PHI is
    - Individually identifiable health information (IIHI)
    - Transmitted or maintained in any form or medium (paper, oral, electronic)
    - Created or received by a covered entity, business associate or employer
    - Relating to health care or payment

HIPAA Privacy Rule

- Exceptions to authorization requirement:
  - Research of de-identified records, data or tissue, DNA or blood samples
    - "Safe Harbor" removal of 18 specified identifiers
  - Preparatory to research – with representations from researcher
  - Limited data set – with data use agreement
    - Stripped of specific direct identifiers
  - Health information created by a non-covered entity (e.g., industry sponsor)

Points to Consider

- Understand who is a CE and subject to the Privacy Rule (an industry sponsor is likely not)
- Ensure clear explanation of the intended use and disclosure of collected data/specimens
- Ensure the use and disclosure is consistent with the purpose and activities of, and specific to the study
- Ensure inclusion of informed consent and authorization required core elements and statements

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State Law

- Personal access to DNA results
- Informed consent and exemptions
- Retention and destruction of DNA samples and genetic information
- Disclosure of results
- Property interests
- Liability for noncompliance

Examples of State Laws Addressing Informed Consent and Exemptions

- New Mexico
  - "[N]o person shall obtain genetic information or samples for genetic analysis from a person without obtaining informed and written consent from the person or the person's authorized representative." N.M. Stat. Ann § 24-21-3.

Examples of State Laws Addressing Informed Consent and Exemptions

- **Nevada**
  - "**It is unlawful to obtain any genetic information of a person without first obtaining the informed consent of the person or the person's legal guardian pursuant to NRS 629.181, unless the information is obtained:** (1) By a federal, state, county or city law enforcement agency to establish the identity of a person or dead human body; (2) To determine the parentage or identity of a person pursuant to NRS 56.020; (3) To determine the paternity of a person pursuant to NRS 126.121 or 425.384; (4) **For use in a study where the identities of the persons from whom the genetic information is obtained are not disclosed to the person conducting the study**; (5) To determine the presence of certain inheritable disorders in an infant pursuant to NRS 442.115 or a provision of federal law; or (6) Pursuant to an order of a court of competent jurisdiction." Nev. Rev. Stat. § 629.151.

State Law: Informed Consent and Exemptions

- **Oregon**
  - "A person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research only if the individual: (A) Has granted informed consent for the specific anonymous research or coded research project; (B) Has granted consent for genetic research generally; (C) Was notified in accordance with ORS 192.538 (Notice by health care provider regarding anonymous or coded research) that the individual's biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the individual did not, at the time of notification, request that the biological specimen or clinical individually identifiable health information not be used for anonymous research or coded research. . . " Or. Rev. Stat. § § 192.537-192.538.

State Law: Informed Consent and Exemptions

- **Alaska**
  - "Except as provided in (b) of this section, (1) a person may not collect a DNA sample from a person, perform a DNA analysis on a sample, retain a DNA sample or the results of a DNA analysis, or disclose the results of a DNA analysis unless the person has first obtained the informed and written consent of the person, or the person's legal guardian or authorized representative, for the collection, analysis, retention, or disclosure;" Alaska Stat. § 18.13.010 .

State Law: Informed Consent and Exemptions

- **Delaware**
  - "… 'Informed consent' (a) For the purpose of obtaining genetic information, means the signing of a consent form which includes a description of the genetic test(s) to be performed, its purpose(s), potential uses, and limitations and the meaning of its results, and that the individual will receive the results unless the individual directs otherwise; (b) For the purpose of retaining genetic information, means the signing of a consent form which includes an description of the genetic information to be retained, its potential uses and limitations; (c) For the purpose of disclosing genetic information, means the signing of a consent form which includes a description of the genetic information to be disclosed and to whom." Del. Code Ann. tit. 16, § 1220.

Examples of State Laws Addressing Privacy and Ownership of Genetic Information

Alaska:

- "[A] DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed." Alaska Stat. § 18.13.010(a)(2).

Colorado:

- "Genetic information is the unique property of the individual to whom the information pertains." Colo. Rev. Stat. Ann. § 10-3-1104.7(1)(a).

Florida:

- "[T]he results of such DNA analysis, whether held by a public or private entity, are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested." Fla. Stat. Ann. § 760.40(2)(a).

Examples of State Laws Addressing Privacy and Ownership of Genetic Information

Georgia:

- "Genetic information is the unique property of the individual tested." Ga. Code Ann. § 33-54-1(1).

Louisiana:

- "An insured's or enrollee's genetic information is the property of the insured or enrollee." La. Rev. Stat. Ann. §22:1023(E).

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Changes to HIPAA – ARRA/HITECH

- Subtitle F of HIPAA- Amended by HITECH Act (part of ARRA)
  - Strengthens federal privacy and security provisions to protect PHI and e-PHI, including notification requirements for health data security breaches
  - Business Associates are now directly subject to certain aspects of HIPAA
    - Responsibility for its uses and disclosures of PHI.
    - Subject to HIPAA's civil and criminal enforcement.
    - Required to take reasonable steps to cure a CE's material breach or violation of a BAA

Changes Affecting HIPAA - GINA

- The Genetic Information and Nondiscrimination Act of 2008 (GINA) prohibits insurers from:
  - Requesting or requiring genetic testing of an individual or his family;
  - Using genetic information to make hiring /promotional decisions or determining eligibility for training programs.
- Under GINA "genetic information" is treated as "health information" for purposes of HIPAA.
  - Genetic Information under GINA means information about "genetic tests" of the individual or his/her "family member" and the manifestation of disease/disorder in family members of the subject.

Changes Affecting HIPAA – GINA, cont.

  - "Genetic test" is the analysis of human DNA, RNA, chromosomes, proteins or metabolites which detect genotypes, mutations, or chromosomal changes.
  - An important exception to the definition of "genetic test" is "an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological conditions that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved" is not a genetic test.
- Thus, if "genetic information" is PHI and protected by HIPAA, a valid authorization to use and disclose that "genetic information" must be obtained.

Resources

- **OHRP Resources**
  - 45 CFR Part 46 available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
  - Informed Consent available at: http://www.hhs.gov/ohrp/policy/consent/index.html
  - Biological Materials and Data available at: http://www.hhs.gov/ohrp/policy/biodata/index.html
  - Checklists and Decision Trees available at: http://www.hhs.gov/ohrp/policy/checklists/index.html
- **FDA Resources**
  - 21 CFR Part 50 available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50
  - 21 CFR Part 56 available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56
- **HHS Health Information Privacy - Regulation Text of All Rules**
  - HIPAA available at: http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/adminsimpregtext.pdf

Resources

- Organization of European Cancer Institutes (OECI),
  Marco A. Pierotti (Milan) and Claudio Lombardo (Genoa),
  From the biobank to the research biorepository: ethical and legal recommendations. An initiative of the Independent Ethics Committee
  Fondazione IRCCS"Istituto Nazionale dei Tumori – Milano".
  www.oeci.eu
- **SYMPOSIUM: Enforcing the Rights of Human Sources to Informed Consent and Disclosures of Incidental Findings from Biobanks and Researchers: State Mechanisms in Light of Broad Regulatory Failure**
  - 13 Minn. J.L. Sci. & Tech. 575
  - **Note: "The Life Of The Flesh Is In The Blood" 1: State Storage And Usage Of Baby's Blood Sample**
    - 18 Cardozo J.L. & Gender 753

  •Minnesota Supreme Court held that an individual's blood samples were biological information subject to protection under Minn. law. The newborn screening statutes provided an exception only to the extent that the Department was authorized to administer newborn screening
    - Bearder v. State, 806 N.W.2d 766 (Minn. 2011)

Closing

- **Questions and Answers**

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