

Advancing Rare Disease Research: The Intersection of Patient Registries, Biospecimen Repositories, and Clinical Data

State Law Issues

Jack Schwartz

- 1) In research settings anywhere in the United States, the primary focus of legal and regulatory compliance is on *federal* statutes (e.g., HIPAA) and regulations (e.g., 45 CFR Part 46, Subpart A, the Common Rule) affecting clinical and research settings. This emphasis is appropriate, because federal law:
 - a) Applies uniformly throughout the country; and
 - b) Must be followed whenever an activity is subject to it.

- 2) Federal law, however, should not be the sole focus of attention. State law might:
 - a) Add protections to those afforded by federal law;
 - b) Extend requirements paralleling federal law to activities not subject to federal law directly; or
 - c) Address matters omitted from federal law.

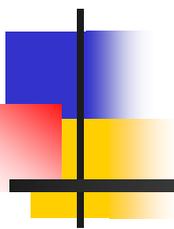
- 3) Think of a pair of tangent circles, the larger being federal law and the smaller state law.
 - a) Better, think of a large circle with many smaller tangent ones, because of substantial variance from one state to another.

- 4) Important cautionary note about one form of state law:
 - a) On some topics, the law of a state is formed through appellate court decisions (common law), rather than statutes (enactments by the legislature) or regulations (enactments by administrative agencies).
 - b) Consequently, in many states the “law” about a particular question is unknown, or simply a matter of speculation, until a court addresses it.
 - c) Example: participation by children in research
 - i) Under settled common law in every state, parents have broad legal authority to make decisions on behalf of their children, in health care and a wide range of other matters.
 - ii) Under settled common law in every state, the general standard that governs parental decision making is the best interest of their children.

- iii) How does the best interest standard apply to parental decision making about their children's participation in research?
 - iv) In one state, Maryland, the best interest standard has been interpreted by the state's highest appellate court (the Maryland Court of Appeals) to mean that parents may *not* allow their children to become subjects in most "no-expected-benefit" research, even if the children's participation would be permissible under federal regulations (45 CFR Part 46, Subpart D).
 - (1) Relevant case citation: *Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 782 A.2d 807 (2001).
 - v) Is this the law in other states?
 - (1) Not yet, given no court decision on point other than in Maryland.
 - vi) Might it become the law of another state?
 - (1) Could be, depending on future litigation.
 - (2) Prudent planning calls for awareness of this possibility.
- 5) Examples of relevant issues potentially affected by state law:
- a) Informed consent in the clinical setting
 - i) If part of a pathology specimen is to be used for research purposes, what description of the research, or of the physician's role in the research, must be given to the patient?
 - (1) Relevant case citation: *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 793 P.2d 479 (1990).
 - ii) If DNA testing is to be done on a biospecimen, are any special informed consent requirements imposed?
 - (1) State statutory example: Michigan Public Health Code § 333.17520.
 - b) Disclosure of medical records for research purposes
 - i) Does state law impose requirements more stringent than HIPAA or potentially affect redisclosure to other researchers?
 - (1) State statutory example: Maryland Health-General Code § 4-302(d).
 - c) Return to subjects of clinically relevant information
 - i) Does state law affect the question whether any research results are returned to the subjects?
 - (1) No cases yet; see the argument about fiduciary obligations in Greely HT 2007. "The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks." *Annual Review of Genomics and Human Genetics* 8:343-364.
 - d) Property interest in biospecimens or products derived from them
 - i) Example 1: If a patient advocacy group facilitates research by assembling information and promoting biospecimen collection, and a researcher uses this information and material to identify a disease-causing gene, what control does the group have over the subsequent economic exploitation of the researcher's discovery?

- (1) Relevant case citation: *Greenberg v. Miami Children's Hospital Research Institute*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).
- ii) Example 2: If research participants support the work of a particular researcher by donating biospecimens, and the researcher then moves to a different university, do the research participants have a right to transfer the biospecimens along with the researcher?
- (1) Relevant case citation: *Washington University v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006), *affirmed*, 490 F.3d 667 (8th Cir. 2007).
- 6) Take-home message: For any of these issues, make sure that a knowledgeable person has considered what impact, if any, state law has on a proposed activity.

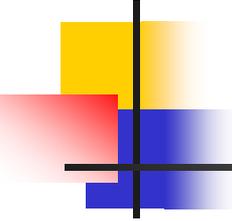
State Law Issues in Medical Research & Release of Genetic Information



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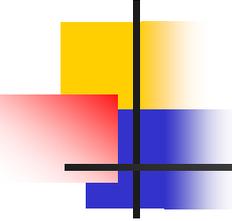
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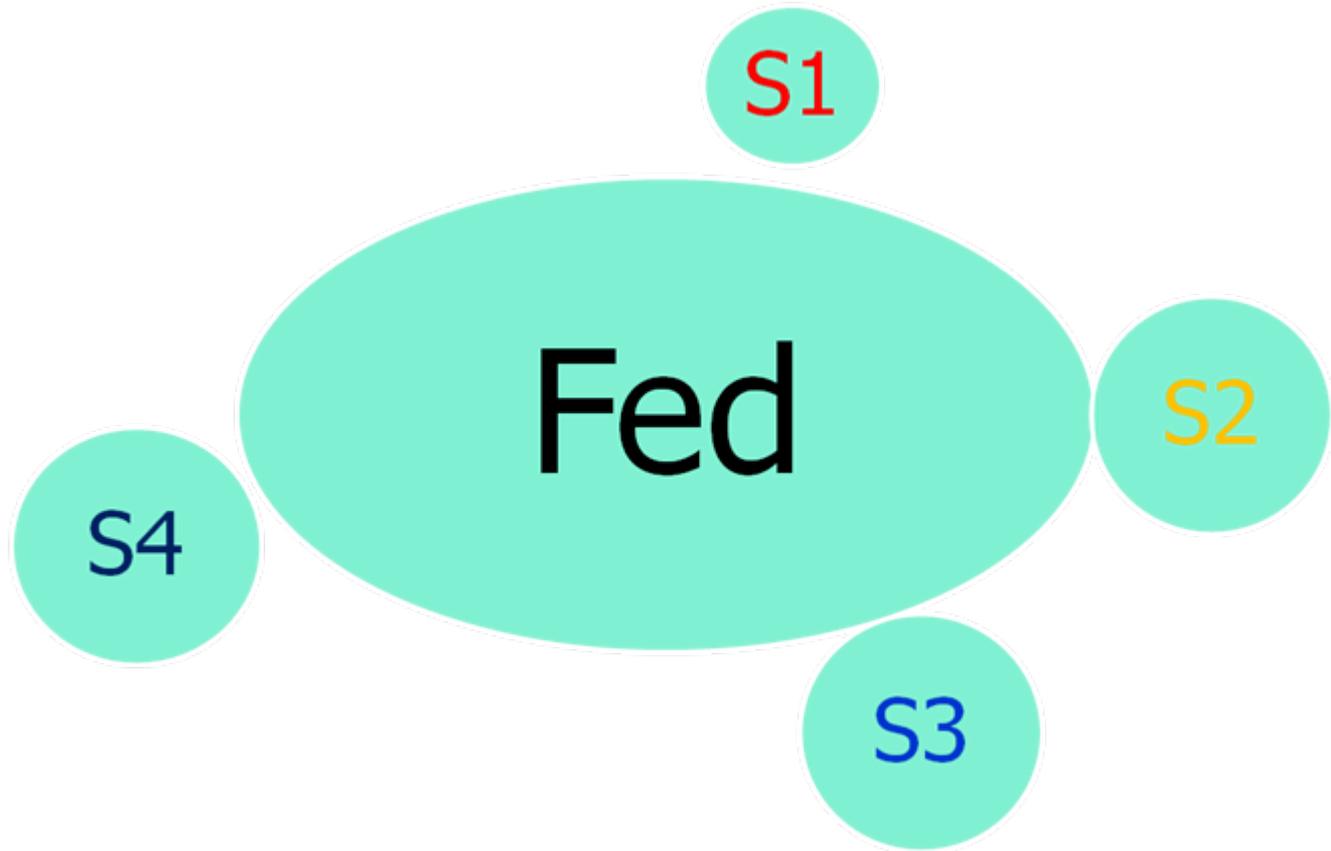


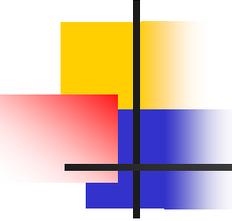
Why Does State Law Matter?

- Federal law (statutes, regulations) is not the whole story
- State law can
 - Add protections
 - Answer questions left open by federal law
 - Establish rights/duties in areas not covered by federal law



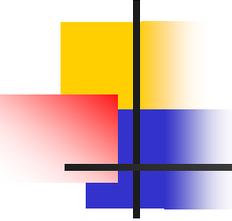
Federal and State Law





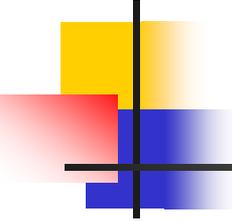
Sources of State Law

- Statute
 - Enacted by legislature
 - Sometimes with later court interpretation
- Regulation
 - Enacted by administrative agency
- Court decision itself (“common law”)



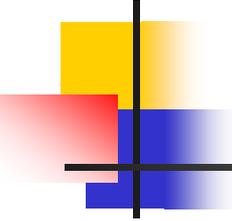
State Law: Lower Viscosity

- State legislatures can act fairly quickly
 - Example: Maryland statute on research after death of healthy volunteer at Hopkins
- Outcome of single lawsuit can affect other researchers
 - Example: court decision in lead paint case affecting all pediatric research in Maryland
 - *Grimes v. Kennedy Krieger Institute*, 782 A.2d 807 (Md. 2001).



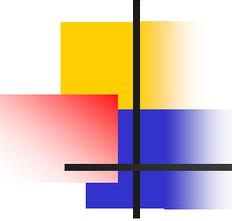
State Law Points to Consider

- Informed consent process
 - Any state-specific requirements for research informed consent?
 - Any state-specific requirements for genetic testing?
 - Duty to disclose potential commercial development of biospecimen-derived product?
 - *Moore v. Regents*, 793 P.2d 479 (Cal. 1990)



State Law Points to Consider

- Disclosure of medical records
 - Does state law add anything to HIPAA?
 - Example: One-year expiration of release
- Ownership and use of biospecimens
 - How do state property and gift law affect relationship between donors, researchers, and research institutions?
 - *Moore, Greenberg, Catalonia*
 - What law applies to contracts involving donated biospecimens?



Take-Home Points

- Do not assume that federal compliance = all required compliance
- When obtaining or sharing health information/biospecimens, find out whether state law has any impact