



Providing Newborn Screening Specimens for Research Legal Issues Faced by State Health Departments

Public Health Law Association
Virtual Seminar, August 24, 2010
Denise Chrysler, Presenter

Outline & Resources

1. Introductory comments
2. Government authority regarding newborn screening specimens / data
 - a. Retention and storage
 - b. Making specimens available for research
3. Ownership and control of specimens
 - a. Litigation regarding ownership and control of tissues (*Moore, Catalona, Greenberg, Havasaupi Tribe*)
 - b. Litigation regarding newborn screening specimens (*Beleno v. Tex. Dept. of State Health Services, Bearder v. Minnesota*)
 - c. Consent: opt-in; opt-out; no opportunity for consent/dissent; informed consent; re-consent
 - d. Control: request for return or destruction of specimen
 - e. State law
 - f. Common Rule (Regulations for the Protection of Human Research Subjects)
 - g. Biorepositories: storing specimens for potential research
 - h. HIPAA privacy rule: privacy board review; data use agreements
 - i. Privacy: are dried blood spots "identifiable"?
 - j. Safeguards to protect confidentiality: double coding, honest broker, designated medical research project (Michigan), certificate of confidentiality (federal)
 - k. Laws that protect genetic privacy; laws that prohibit discrimination based on genetic information
 - l. Transparency; parent education; community engagement; community values advisory board

4. Ownership and control of research results
 - a. Promoting research: collaborative research communities vs. competition/harvesting the fruits of your own labor
 - b. Public asset/public benefit
 - c. Charitable trust model
 - d. Intellectual property
 - e. Patents on genes (BRCA litigation)
 - f. Material transfer agreement (MTA)
 - g. Notifying individual test subjects of research results
 - h. Transparency; parent and community engagement; community values advisory board

5. Legal issues related to the development and operation of a program to manage the availability of newborn screening specimens for research
 - a. Structure / partners
 - b. Management agreement
 - c. Fees
 - d. MTAs
 - e. Data Use Agreements
 - f. Acceptable uses
 - g. Finite materials and priorities
 - h. Review for scientific merit

6. Selected links and resources
 - a. Michigan-related resources
 - i. Michigan's newborn screening program:
<http://www.michigan.gov/newbornscreening>
 - ii. Michigan BioTrust for Health, Michigan's initiative to provide newborn screening specimens for research:
<http://www.michigan.gov/biotrust>
 - iii. Report of the Michigan Commission on Genetics and Progress (1999):
http://www.michigan.gov/documents/GeneticsReport_11649_7.pdf
 - iv. Michigan Neonatal Biobank, Inc., a non-profit 501(c)3 Michigan corporation created by Wayne State University, Michigan State University, University of Michigan, and the Van Andel Institute to store and manage the Department of Community Health's collection of newborn screening specimens: <http://www.mnbb.org>
 - b. Office for Human Research Protections: <http://www.hhs.gov/ohrp/>
 - i. OHRP guidance on tissue repositories
<http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>
 - ii. OHRP guidance on research involving coded information
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>
 - c. HIPAA Privacy Rule:
 - i. Office for Civil Rights materials: <http://www.hhs.gov/ocr/privacy>

- ii. Educational materials on HIPAA and public health, HIPAA and Research, HIPAA and information technology, HIPAA and genetic information:
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/index.html>
- iii. HIPAA Privacy Rule and Public Health, Guidance from CDC and the U.S. Department of Health and Human Services:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>
- iv. National Institutes of Health materials regarding HIPAA and research: <http://privacyruleandresearch.nih.gov>
- d. National Institutes of Health, Office of Technology Transfer, provides models and forms including material transfer agreements, cooperative research and development agreements, licensing and royalty agreements:
<http://www.ott.nih.gov/index.aspx>
- e. Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening, [HHS] Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, Briefing Paper (draft):
<http://www.hrsa.gov/heritabledisorderscommittee/RBSBriefingPaperFINALDraft42310.pdf>
- f. Institutes of Medicine, Challenges and Opportunities in Using Newborn Screening Samples for Translational Research: A Workshop, May 24, 2010, <http://iom.edu/Activities/Research/GenomicBasedResearch/2010-MAY-24.aspx>. See, for example:
 - i. Current State Policies and Practices: Storage and Use of NBS Samples, Presented by Alissa Johnson:
<http://iom.edu/~media/Files/Activity%20Files/Research/GenomicBasedResearch/Presentations%20Newborn%20Screening/JohnsonMay%2024.pdf>
 - ii. Rationale for Storing NBS Specimens, Presented by *K Pass, Biggs Laboratory*, See slides 10-12 for a list of 162 published uses of Analytes Measured in Dried Human Blood on Filter Paper (Information courtesy of Harry Hannon, CDC):
http://www.iom.edu/~media/Files/Activity%20Files/Research/GenomicBasedResearch/Presentations%20Newborn%20Screening/Pas_s_May%2024.pdf
- g. David E. Winickoff and Richard N. Winickoff, The Charitable Trust as a Model for Genomic Biobanks, *N Engl J Med*, September 18, 2003, p. 1180. <http://www.nejm.org/doi/full/10.1056/NEJMs030036>
 - i. Website of PXE International (discussed in "Charitable Trust" article) a nonprofit that maintains a collection of biological samples and clinical information used by qualified scientists to further research on pseudoxanthoma elasticum (PXE): <http://www.pxe.org> See <http://www.pxe.org/english/view.asp?x=1827&id=114> for description of infrastructure.

- h. Amy L. Fairchild, et al., Public Goods, Private Data: HIV and the History, Ethics, and Uses of Identifiable Public Health Information, *Public Health Law Reports*, 2007 Supplement 1, Vol. 122, p. 7.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1804110/pdf/phr122S10007.pdf>
- i. *The Immortal Life of Henrietta Lacks*, by Rebecca Skloot: (Feb. 2010, Crown Publishing Group, 384 pages; also available in audio and Kindle editions). Puts a human face on research subjects and their families.
- j. Malcolm Gladwell, Annals of Innovation, "The Treatment," *The New Yorker*, May 17, 2010, p. 69. Examines the challenges in developing cancer drugs. Puts a "human face" on biotechnology companies and their researchers.
http://www.newyorker.com/reporting/2010/05/17/100517fa_fact_gladwell?printable=true (abstract, subscription or fee required for full text)

7. Cases

- a. *Moore v California Regents*, 51 Cal 3d 120 (1990)
http://www.eejlaw.com/materials/Moore_v_Regents_T08.pdf
- b. *Greenberg v Miami Children's Hosp*, 264 F Supp 2d 1064 (SD Fla 2003)
<http://indylaw.indiana.edu/instructors/orentlicher/healthlw/Greenberg.htm>
(Excerpts from opinion)
- c. *Washington University v Catalona*, 490 F 3d 667 (8th Cir, 2006)
<http://prostatecure.wustl.edu/pdf/8thCircuitOpinion.pdf>
- d. *Bearder v State of Minnesota* (2009):
<http://www.bioethics.iu.edu/body.cfm?id=133> (Provides links to selected docket materials).
- e. *Beleno v. Tex. Dept. of State Health Services* (2009):
<http://www.bioethics.iu.edu/body.cfm?id=133> (Provides links to selected docket materials).
- f. *Havasupai Tribe v. Arizona Board of Regents, et al.* Cause No. CV20005-013190. Arizona Court of Appeals.
<http://www.cofad1.state.az.us/opinionfiles/CV/CV070454.pdf>
- g. *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.* <http://docfiles.justia.com/cases/federal/district-courts/new-york/nysdce/1:2009cv04515/345544/256/0.pdf>



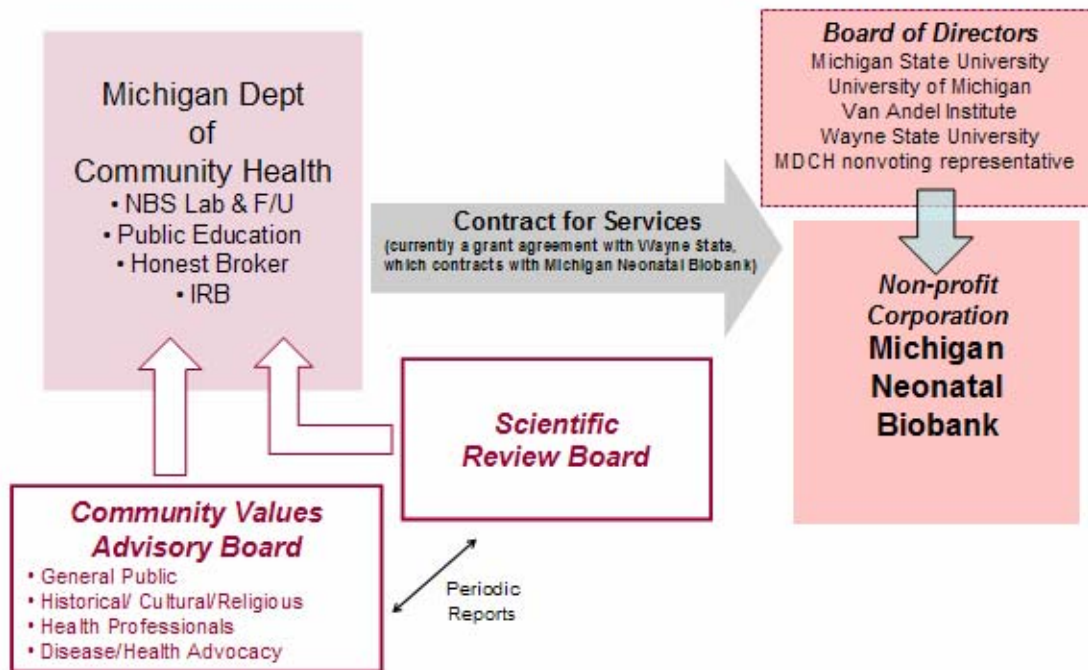
Denise Chrysler, J.D.
Michigan Department of Community Health
Public Health Administration
Public Health Legal Director
(517) 373-2109
chryslerd@michigan.gov

Note: I will be leaving the Michigan Department of Community Health August 31, 2010 and joining the University of Michigan School of Public Health, Center for Law, Ethics, and Health, in mid-September. In the interim, do not hesitate to contact me at my personal e-mail address: paulprattdchrysler@sbcglobal.net.

Michigan Department of Community Health contacts:

- Janice Bach (policy), BachJ@michigan.gov, 517-335-8497
- Carrie Langbo (informed consent process and outreach), LangboC@michigan.gov, 517-335-6497
- Harry McGee (IRB), McGeeH@michigan.gov, 517-241-0806
- Frances Downes (laboratory), DownesF@michigan.gov, 517-241-0048
- Matthew Rick (office of legal affairs), RickM@michigan.gov, 517-241-0048

Michigan BioTrust for Health Governance/Advisory Structure



Michigan's Community Values Advisory Board includes representatives from the following organizations/interests: American Cancer Society (Great Lakes Division), American Civil Liberties Union of Michigan, Arab Community Center for Economic and Social Services, Cristo Rey, Faith Access to Community Economic Development, Inter-Tribal Council, Michigan Association of Genetic Counselors, Health Law Attorney, March of Dimes (Michigan Chapter), MichBio, Michigan Council for Maternal & Child Health, Michigan Developmental Disabilities Council, Michigan Environmental Council, Michigan Minority Health Coalition, Michigan Health and Hospital Association, Michigan Osteopathic Association, National Alliance on Mental Illness Michigan, Newborn Screening Parent.