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Biobanking Newborn Bloodspots for Genetic Research Without Consent

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BIOBANKING NEWBORN BLOODSPOTS FOR GENETIC RESEARCH WITHOUT CONSENT

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[I]n the not too distant future . . . part of the newborn screen . . . will be to look at all of the DNA and make a solid prediction about what that child needs to watch out for. This is a real revolution in medicine, probably unlike anything that has happened since antibiotics were introduced.[1]

INTRODUCTION

State public health programs mandate newborn screening shortly after birth for various genetic disorders that may have serious health consequences if not identified and treated very early in life. Given the individual and public health benefit, most of states conduct newborn screening programs ("NBS programs") without parental consent. Recently, two high–profile lawsuits have alerted the public of the fact that some states are creating research biobanks,[2] storing their newborn bloodspots, and disseminating them to outside entities for genetic research purposes that are unrelated to the original purpose for which the bloodspots were obtained.[3]

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1. Francis S. Collins, *The Language of Life: DNA and the Revolution in Personalized Medicine*, YOUTUBE (Dec. 21, 2009), http://www.youtube.com/watch?v=8qxMbP2gWpU (promoting Dr. Collins' book).

2. A biobank may be defined as "any collection of human biological material—organs, tissue, blood, cells and other body fluids—that contains sdf at least traces of DNA or RNA that would allow genetic analysis." Bernice S. Elger & Arthur L. Caplan, *Consent and Anonymization in Research Involving Biobanks*, 7 EMBO REPORTS 661, 661 (2006); *see also* Mark A. Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J.L. MED. & ETHICS 89, 89 (2005) ("Biobanks are repositories of human biological materials collected for biomedical research.").

3. *See infra* Part II.

That newborn bloodspots are a valuable scientific tool, with great potential for the public good, is not disputed. Newborn screening specimens are valuable for medical research that can improve the health of children and provide critical information about the roots of both child and adult diseases.[4] What is troublesome, however, is that newborn screening programs, almost universally, do not obtain informed consent from the newborn's parent, guardian, or managing conservator.[5] If, however, the purpose of the blood collection is two–fold—newborn screening for disease on the one hand, and genetic research on the other—then collecting newborn blood samples without parental consent raises serious ethical and legal issues.

This article begins with a brief overview of the NBS programs common to all fifty states.[6] Part II examines the claims made in lawsuits in Texas and Minnesota.[7] This article then goes beyond the issues presented in the lawsuits, and addresses the larger concern of how to maintain the public's trust in state newborn screening programs as medical research progresses, and newborn bloodspots become an essential and highly sought–after research tool.[8] Part III examines whether the federal regulations for the protection of human research subjects, and federal guidelines for establishing research biobanks, ought to apply to state newborn screening programs, in light of extensive and increasing federal involvement in these programs.[9] Part IV analyzes the concept of informed consent in the context of newborn screening and research,[10] and Part V reveals the underlying fallacy of presumed consent in the genetic research context.[11] This article concludes that states should adopt the federal regulations for the protection of human research subjects, and the federal guidelines for establishing biobanks, and require, prior to the point of blood

4. SEC'YS ADVISORY COMM. ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN, HEALTH RES. & SERVS. ADMIN., DRAFT BRIEFING PAPER: CONSIDERATIONS AND RECOMMENDATIONS FOR NATIONAL GUIDANCE REGARDING THE RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT SPECIMENS AFTER NEWBORN SCREENING ii (2010) [hereinafter SEC'YS ADVISORY COMM. PAPER], *available at* http://www.hrsa.gov/heritabledisorderscommittee/reports/.

5. *See* KATHERINE DRABIAK–SYED, IND. UNIV. CTR. FOR BIOETHICS, NEWBORN BLOOD SPOT BANKING: APPROACHES TO CONSENT 1 (2010), *available at* http://bioethics.iu.edu/index.php/download_file/view/91/ ("Most states do not inform parents of retention and research use of NBS; early screening tests can prevent avoidable injuries to newborns. Accordingly, many state health departments do not obtain consent before storing and using the NBS for further research.").

6. *See infra* Part I.

7. *See infra* Part II.

8. *See infra* Parts III–V.

9. *See infra* Part III.

10. *See infra* Part IV.

11. *See infra* Part V.

collection, written parental consent to biobank newborn bloodspots for future genetic research.[12] The critically important message of this article is that if states are not forthcoming with parents regarding use of their child's blood for genetic research, they risk a potentially disastrous result—undermining the public's trust in essential newborn screening programs.

I. NEWBORN SCREENING PROGRAMS

Every year in the United States, nearly four million newborn babies have their little heels pricked and squeezed to disgorge several drops of blood that will be placed on a "Guthrie card," which consists of special filter paper containing the bloodspot, as well as identifying information such as the mother's name, hospital of birth, baby's medical record number, doctor's name, and other clinical information.[13] The blood specimens are air dried, and sent to a laboratory where the blood will be screened for a variety of illnesses.[14] The blood specimens are accompanied with identifying and demographic information, as well as physician or other appropriate contact information.[15] The screening, which is primarily genetic screening, is authorized by State public health initiatives that currently exist in all fifty states.[16] Genetic screening refers to screening for "heritable disorders that are caused by abnormalities in the individual's genes and chromosomes."[17] The collective purpose of newborn screening programs is to screen the entire population for the presence of an illness before any

12. *See infra* Part V.

13. For a sample Guthrie card, see *Newborn Screening for Genetic Conditions*, CENTRE FOR GENETICS EDUC., http://www.genetics.com.au/factsheet/fs20.asp (last visited May 2, 2011) (listing information collected, including mother's name, hospital of birth, doctor's name, baby birth weight, and date of birth, and providing a visual example of the Guthrie card).

14. *See, e.g.*, 25 TEX. ADMIN. CODE § 37.55(c) (2011) ("Blood specimens must air-dry on a flat surface for at least four hours and must be mailed to the department within 24 hours after collection.").

15. *See, e.g.*, 25 TEX. ADMIN. CODE § 37.55(d) ("Providers shall ensure that the identifying and demographic information sheet is complete and . . . [i]dentifying information shall include contact information for the newborn's physician or health care practitioner to ensure ability to contact . . . in case of an abnormal screen.").

16. *See* PRESIDENT'S COUNCIL ON BIOETHICS, THE CHANGING MORAL FOCUS OF NEWBORN SCREENING 5–6 (2008), *available at* http://bioethics.georgetown.edu/pcbe/reports/newborn_screening (explaining that screening "is almost entirely *genetic* screening," and that screening is conducted on the entire population).

17. *See id.* at 6 & n.3 (noting that a few states also screen for infectious diseases such as HIV). *See generally* NAT'L NEWBORN SCREENING & GENETIC RES. CTR., NATIONAL NEWBORN SCREENING STATUS REPORT (2011), *available at* http://genes-r-us.uthscsa.edu/nbsdisorders.pdf (listing the status of newborn screening in the United States by state as of January 18, 2011).

symptoms of disease are exhibited, on the premise that early identification of a disease might make the difference between life and death.[18]

Newborn babies have been screened shortly after birth for over forty years. In the 1960s microbiologist Robert Guthrie developed a simple, inexpensive, test (the "Guthrie Test") for the presence of Phenylketonuria ("PKU"), a rare genetic metabolic disorder that, if left untreated, generally results in severe mental and behavioral disabilities.[19] Even though PKU is quite rare, affecting only about 1 in 11,000 births, the resulting developmental disability is preventable if the PKU newborn is placed on a special diet;[20] once the retardation occurs, however, it cannot be reversed. [21] Thus, it became essential to test for PKU quickly. The Guthrie Test met this need, since it could be administered shortly after birth. [22] After a successful two year clinical trial involving over 400,000 infants, a massive public campaign, backed by President Kennedy and the newly–created Presidential Advisory Commission on Mental Retardation, was undertaken to encourage states to adopt mandatory newborn screening legislation.[23] Through the years, medical knowledge and testing technology advanced significantly, allowing laboratories to screen for many different conditions. Today, all fifty states have mandatory NBS programs, although the number of screened–for conditions varies among states.[24] The American College of Medical Genetics, in its effort to develop a test panel that could be adopted uniformly by the states, recommends screening for 29 core conditions, and another 25 conditions that could be detected when screening for the core

18. *See* CTR. FOR BIOETHICS, UNIV. OF MINN., NEW FRONTIERS IN GENETIC TESTING AND SCREENING 7 (1999), *available at* http://www.ahc.umn.edu/img/assets/26104/Genetic_Testing.pdf (describing the purpose of genetic screening for newborns and detailing some of the diseases and conditions that can be treated if caught early enough).

19. Diane B. Paul, *The History of Newborn Phenylketonuria Screening in the U.S.*, *in* FINAL REPORT OF THE TASK FORCE ON GENETIC SCREENING (Neil A. Holtzman & Michael S. Watson eds., 1997), *available at* http://biotech.law.lsu.edu/research/fed/tfgt/appendix5.htm. The Task Force Report was created by the National Institute of Health Department of Energy Working Group on Ethical, Legal, & Social Implications ("ELSI") of the Human Genome Research Project. Its purpose was "to review genetic testing in the United States and make recommendations to ensure the development of safe and effective genetic tests." *Executive Summary*, *in* FINAL REPORT OF THE TASK FORCE ON GENETIC SCREENING (Neil A. Holtzman & Michael S. Watson eds., 1997), *available at* http://biotech.law.lsu.edu/research/fed/tfgt/index.htm#EXECUTIVE.

20. *See* CTR. FOR BIOETHICS, *supra* note 18, at 7 (noting that PKU can be controlled by diet); Paul, *supra* note 19 (noting the rarity of PKU).

21. Paul, *supra* note 19.

22. *Id.*

23. *Id.*

24. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 16, at 7 (noting that, depending on the state of birth, an infant will likely be screened for between 29 and 54 conditions).

conditions.[25] Today, most states screen for all or nearly all of the 29 core conditions.[26]

NBS programs "represent the most comprehensive population testing program" in existence, with "specimens . . . obtained from essentially every newborn" in the United States.[27] Although educational pamphlets about the screening program are typically distributed to the parent, guardian, or managing conservator, (hereinafter "parent"), state statutes, almost universally, do not require NBS programs to obtain the informed consent of the newborn's parent prior to extracting the blood sample.[28]

Informed consent, now widely codified into state medical practice legislation, is firmly rooted common law concept that recognizes the right of self–determination, and promotes individual autonomy in making medical decisions concerning one's own body, as well as the bodies of one's children.[29] It reflects the moral belief that physicians must not inflict

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25. *See* Mary Ann Baily, *Newborn Screening*, *in* FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 125–28 (Mary Crowley ed., 2008), *available at* http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/newborn%20screening%20chapter.pdf (listing core conditions and discussing ethical controversies in newborn screening).

26. *Id.* at 125. Unlike PKU, some of these conditions have no effective treatments. *See* Donald B. Bailey, Jr., *The Blurred Distinction Between Treatable and Untreatable Conditions in Newborn Screening*, 19 HEALTH MATRIX 141, 141–42 (2009) (noting that new technologies allow physicians to screen infants for conditions for which medical treatment is unavailable). Newborn screening for conditions that are not presently treatable is highly controversial, and beyond the scope of this article. For insight into the debate surrounding screening for currently untreatable conditions, see generally Jeffrey R. Botkin, *Assessing the New Criteria For Newborn Screening*, 19 HEALTH MATRIX 163, 163–64, 181–83 (2009) (summarizing state newborn screening programs, the expansion in the number of conditions being added to screening tests, and the difficulties involved with adding new tests with the potential benefits are not yet being realized); Ellen Wright Clayton, *Ten Fingers, Ten Toes: Newborn Screening For Untreatable Disorders*, 19 HEALTH MATRIX 199, 200–03 (2009) (discussing newborn screening for untreatable disorders with the movie GATTACA and the various public policies such screening brings to society at large); R. Rodney Howell, *Systems to Determine Treatment Effectiveness In Newborn Screening*, 19 HEALTH MATRIX 155, 156–57 (2009) (commenting on the various collaborative screening and genetics groups around the United States that track newborn screening and the need for long–term information sharing); Marvin R. Natowicz & Shlomit Zuckerman, *On Treatability: Considerations of Treatment In The Context of Newborn Screening*, 19 HEALTH MATRIX 187, 189–93 (2009) (reviewing several newborn screening articles on the subjects of treatability, general population screening and its implications, and the rising costs of screening tests).

27. Bradford L. Therrell et al., *Status of Newborn Screening Programs in the United States*, 117 PEDIATRICS S212, S213 (2006).

28. U.S. GEN. ACCOUNTING OFFICE, GAO–03–449, NEWBORN SCREENING: CHARACTERISTICS OF STATE PROGRAMS 22 (2003), *available at* http://www.gao.gov/new.items/d03449.pdf (noting that only Wyoming's statute requires consent to screen a newborn bloodspot, and that regulations in Maryland also require consent to screen).

29. *See, e.g.*, Schloendorff v. Soc'y of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body[.]").

medical procedures upon their patients against the patient's will.[30] The right to informed consent, and the corresponding duty of the physician to obtain that consent, is not absolute. Legally justified exceptions to the informed consent requirement may exist in circumstances where the exception is necessary for the benefit of the individual, or in the best interests of society.[31] States, through their police power and by virtue of their duty to promote the public welfare, may disregard informed consent requirements where, for example, quarantine is necessary to prevent the spread of infectious disease, or where mass vaccinations are required to control epidemics.[32]

NBS programs undoubtedly present an acceptable use of a state's police power, and the need to implement these programs without the informed consent of the parent may be justified to the extent the programs are designed to identify newborns needing immediate medical care. More recently, however, a disturbing trend has emerged. Some states have gone beyond the original intent of their NBS programs, and have begun storing the baby's blood samples indefinitely for future medical research purposes.[33] One study reveals that, although most states store blood for reasons authorized by statute, such as quality assurance, twelve states retain their blood samples without any officially stated reason.[34] Moreover, great disparity exists among states in the length of time that the samples are retained. As of 2009, South Dakota retains its samples for only one month, but Indiana and New Jersey retain their samples for 23 years.[35] Seven other

30. *See* BARRY R. FURROW ET AL., HEALTH LAW 230 (6th ed. 2008) ("Informed consent has developed out of strong judicial deference toward individual autonomy, reflecting a belief that an individual has a right to be free from nonconsensual interference with his or her person, and a basic moral principle that it is wrong to force another to act against his or her will.").

31. *See, e.g.*, RUTH B. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 35 (1986) (noting that there are five recognized informed consent exceptions, including public health and medical emergencies, incompetency of the patient, therapeutic privilege, and patient waiver).

32. *See id.* at 35–36 (explaining that interventions by public health officials are authorized by law in cases where the adoption of a mass health program is required for the health and safety of an entire population, and that such interventions can include quarantine and mass vaccination requirements).

33. *See* Aaron Joshua Bienstock Goldenberg, Ethics at the Crossroads of Public Health and Biobanking: The Use of Michigan's Residual Newborn Screening Bloodspots for Research 7 (Nov. 19, 2008) (unpublished Ph.D. dissertation, Case Western Reserve University), *available at* http://etd.ohiolink.edu/send-pdf.cgi/Goldenberg%20Aaron.pdf?case1228421146 (noting that many states retain bloodspots after screening, and that a few store them indefinitely and regard them as a "potentially rich source of readily available DNA samples for population based genetic research").

34. Kenneth D. Mandl et al., *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269, 271 (2002).

35. CITIZENS' COUNCIL ON HEALTH CARE, STATE BY STATE GOVERNMENT NEWBORN BLOOD & BABY DNA RETENTION PRACTICES 1–2 (2009), *available at*

states store their samples "indefinitely."[36] A 2006 study revealed that 28 states had no written policy governing storage of residual newborn bloodspots.[37] Specimens that have been stored for more than a few months are no longer satisfactory for confirmation of a newborn's screening results, but the DNA contained in the bloodspot is stable indefinitely.[38] Thus, bloodspots stored longer than a few months are useful primarily for their research potential.[39]

While it may be sensible in the context of a public health initiative to screen newborns for genetic diseases without first obtaining the consent of the parent, this justification does not extend to the subsequent retention and use of the bloodspots for general medical research. When the purpose of state NBS programs is not only for the benefit of the babies who are screened, but also to establish a population–wide repository of baby's blood for future genetic research, the issue becomes more complex. The controversy over retention of baby's blood for future genetic research, without the informed consent of the participants, is at the heart of the two state lawsuits discussed below. The issues raised in the two lawsuits are issues that all States will confront as public awareness regarding genetic research on newborn bloodspots increases. These two lawsuits illustrate how the public's trust in a state NBS program can be undermined by discovery of the state's undisclosed genetic research activities.

II. THE LAWSUITS

A. Texas

Prior to this lawsuit, Texas had the largest baby's blood repository in the country, with over five million stored samples.[40] The Texas Department of State Health Services ("TDSHS") often provided blood samples to other states, without any published guidelines addressing the type of research that

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http://www.cchfreedom.org/pdf/50_States–Newborn_Blood_Retention_Policies_FINAL.pdf (providing sample retention data for all fifty states and the District of Columbia). The Council used data compiled by the National Newborn Screening Information System (http://genes–r–us.uthscsa.edu/). *Id.* at 3 n.1.

36. *Id.* at 1–2. These states are: California, Maine, Michigan, Minnesota, North Carolina, Tennessee, and Vermont. *Id.*

37. Therrell et al., *supra* note 27, at S219.

38. *Id.* at S221.

39. *Id.* at S221–22.

40. *See* Peggy Fikac, *Infant Blood Samples to Be Discarded: State Agrees to Destroy Them After Millions Kept Without Permission: Plaintiff Says She Wants Children's Privacy Respected*, HOUS. CHRON., Dec. 23, 2009, at B1 (noting that the state of Texas will destroy 5.3 million newborn bloodspots taken legally, but without parental consent, in settlement of lawsuit).

could be conducted using the samples.[41] Before the lawsuit, the state had distributed newborn bloodspots for research projects ranging from various University–sponsored disease studies, to the creation of a Department of Defense–sponsored international database designed to aid in criminal investigations and other forensic endeavors, and to for–profit companies' development of more effective screening test–kits.[42]

Texas law requires all newborns to be screened for 29 core disorders within 48 hours of birth, and again at the two–week newborn check–up.[43] Prior to recently passed legislation, parents could object to the screen only if screening would conflict with their religious tenets.[44] Once the screening was complete, the statute limited disclosure of any information related to the screening to diagnosis and medical treatment, and to certain statistical and record–keeping purposes.[45] At the time the Texas lawsuit was filed, the statute did not give the State the authority to retain the samples indefinitely; rather, the statute was silent as to the disposition of the samples after screening was complete, although another statute governing the confidentiality of genetic information provided that samples obtained from individuals for genetic testing must be "destroyed promptly after the purpose for which the sample was obtained is accomplished," with only a few narrow exceptions.[46]

The class action lawsuit was filed in the San Antonio Division of the District Court for the Western District of Texas on March 12, 2009.[47] Plaintiffs, represented by a Texas civil rights attorney, were representative of their respective classes: a recent mother, a father of children born between 2003 and 2007, a mother of children born between 1993 and 1998,

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41. *See* Mary Ann Roser, *State Agency Swaps Babies' Blood for Supplies*, AMER. STATESMAN, May 8, 2010, http://www.statesman.com/news/texas–politics/state–agency–swaps–babies–blood–for–supplies–678302.html (reporting that Texas health officials' practice of providing blood samples from newborns to out–of–state companies and researchers was halted so that the state could develop policy relating to the handling of bloodspots).

42. *See Use of Newborn Screening Blood Spots After Completion of Newborn Screening*, TEX. DEP'T OF ST. HEALTH SERVS. (Feb. 17, 2011), http://www.dshs.state.tx.us/lab/nbsBloodspotsUse.shtm (disclosing previous research uses as part of lawsuit settlement); *see also* Roser, *supra* note 41 (reporting on the non–screening uses to which DNA obtained from bloodspots were put).

43. *See* 25 TEX. ADMIN. CODE § 37.53 (2011) (listing disorders for which newborn screens are required).

44. TEX. HEALTH & SAFETY CODE ANN. § 33.012(a) (West 2010).

45. § 33.014 (governing disclosure of screening test results to certain physicians, parents, or health authorities); *see also* § 33.015 (providing for the authority of health services department to collect data to derive incidence and prevalence rates, and for other statistical and record–keeping purposes).

46. TEX. OCC. CODE ANN. § 58.052 (West 2010).

47. Complaint, Beleno v. Texas Dep't of State Health Servs., No. 5:09–cv–00188–FB (W.D. Tex. Mar. 12, 2009).

the father of a baby born in January 2009, and a pregnant woman expecting her first child in August 2009 (seeking, at the time, prospective relief).[48] The Defendants were employees of the Texas Department of State Health Services (TDSHS), sued in their official capacities and Texas A&M University (the bloodspot storage facility) (collectively, the "State").[49] The Plaintiffs alleged that the State had exceeded its statutory authority to conduct newborn screening for specific diseases, by wrongfully storing 4.2 million NBS samples since July 2002.[50] Nothing in the Texas statute authorized the state to store the samples, or to make them available for future research unrelated to the NBS program. [51] And, Plaintiffs alleged, the State acted secretly, and without the knowledge or consent of the parents.[52] The Plaintiffs sought declaratory and injunctive relief for violation of their Constitutional rights under the Fourth (search and seizure) and Fourteenth (liberty and privacy) Amendments to the U.S. Constitution, and their corresponding state constitutional rights.[53] They also sought an injunction ordering the State to disclose the purposes for which the children's blood has been used and any financial transactions involved, and they sought the destruction of the 4.2 million NBS samples retained by the State.[54]

The State essentially admitted its practice of storing the bloodspots indefinitely and using them for future research purposes, and acknowledged its apparent lack of statutory authority. It defended this practice, however, on the grounds that the bloodspots were lawfully taken (a claim that the plaintiffs did not contest), and that any private genetic information derived from the bloodspots that could conceivably give rise to plaintiffs' constitutional privacy interest claims was protected by adequate security measures.[55] Moreover, the State contended that the use of the bloodspots

48. *See id.* at 2–3 (detailing relevant information about the plaintiffs); *see also* Peggy Fikac, *State to Destroy Blood Samples*, SAN ANTONIO EXPRESS–NEWS, Dec. 23, 2009, at 1B (reporting on the outcome of the *Beleno* lawsuit, and noting that an attorney from the Texas Civil Rights Project prosecuted the lawsuit).

49. *See* Complaint, *supra* note 47, at 3 (detailing relevant information about the defendants).

50. *Id.* at 5–6.

51. *See id.* at 4("Defendants, without any authority or legal justification, have added this practice onto the state's 44 year–old mandated newborn screening program in which hospitals, birthing centers, and midwives draw blood from a baby's heel – no parental consent is required – so the state can test for a variety of birth defects.").

52. *Id.*

53. *Id.* at 5–6.

54. *Id.* at 9.

55. Motion to Dismiss Plaintiffs' Original Complaint at 12–15, Beleno v. Texas Dept. of State Health Servs., No. SA09CA0188–FB (W.D. Tex. May 29, 2009) (relying on *Whalen v. Roe*, 429 U.S. 589, 592–93 (1977) for the proposition that the state retention of private medical information is not an unconstitutional invasion of privacy where the statute that allows the state to collect such information also provided security measures for protection of the information in the state's possession) (on file with author).

for future medical research was governed by the federal HIPAA privacy regulations, which specifically allow for the use and disclosure of protected health information for research purposes once a later, specific, research protocol has been analyzed and approved by an institutional review board ("IRB").[56] With respect to the issue of informed consent, the State contended that, at such time as the samples were used for a specific research project, the federal regulations for the protection of human subjects in medical research would determine the circumstances under which the parent's informed consent would or would not be required. The State rightfully pointed out that privacy concerns differ depending on whether the human subject has been or could be identified from the information released to the researchers. [57] If, the State argued, the regulations required the parental consent for a specific future medical research protocol, that consent could be obtained from the parent at that point in the future.[58]

Barely eleven weeks into the lawsuit, and amidst a flurry of high profile news articles about the pending lawsuit,[59] the Governor of Texas signed into law an amendment to the states newborn screening statute. House Bill No. 1672 plugged one gap in state law by giving the State authority to retain and store the bloodspots, and to release de–identified[60] information relating to the bloodspots for medical research purposes, provided the research had been approved by an IRB.[61]

But the new legislation did not require the State to obtain the written informed consent of the parents. Rather, the legislature instituted an "opt–out," or presumed consent, system. The new system requires the physician attending the newborn to disclose to the parent that the State could legally retain and store the bloodspots, and could subsequently release the bloodspot along with de–identified genetic information, for future research purposes.[62] The physician must also provide the patient with a form that the parent can use if she did not want the State to retain her child's genetic material, or to use it for use it for any purpose outside of the newborn

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56. *Id.* at 16.

57. *Id.* at 17.

58. *Id.*

59. *See infra* notes 188–194 and accompanying text.

60. De–identified information, also called coded or linked information, refers to data that are "separated from personal identifiers through use of a code." *See* SEC'YS ADVISORY COMM. ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN, HEALTH RES. AND SERV. ADMIN., CONSIDERATIONS AND RECOMMENDATIONS FOR NATIONAL GUIDANCE REGARDING THE RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT SPECIMENS AFTER NEWBORN SCREENING 13 (2010),
http://www.hrsa.gov/heritabledisorderscommittee/RBSBriefingPaperFINALDraft42310.pdf

61. H. R. 1672, 81st Leg. (2010), *codified at* TEX. HEALTH & SAFETY CODE ANN. § 33.0111 (West 2010) (requiring the disclosure statement).

62. TEX. HEALTH & SAFETY CODE ANN. § 33.0111(a)–(c) (West 2010).

screening test.[63] The statute does not require the physician who gives the form to the mother–to–be to explain her rights or discuss her options, nor does it require the provider to obtain the completed form from the parent and return it to the State. Thus, the burden is wholly placed on the parent to educate herself regarding her baby's participation in future genetic research, and to complete the form and file it with the TDSHS. Once the Department receives the form, the State has 60 days to destroy the child's genetic material.[64] Otherwise, the State will presume that the parent agrees to have the State store her baby's bloodspot indefinitely, and to release it to outside entities for genetic research.[65]

The new legislation encouraged settlement of the lawsuit, but not until the State agreed to destroy the millions of newborn blood samples that it had stored prior to adoption of the new law, and to publish a list of research projects that had used the bloodspots for genetic research.[66] Due to the settlement, the court did not rule on whether informed consent was required for future medical research on the bloodspots, or whether a presumed consent system was adequate to protect the newborn.[67]

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63. § 33.0112 (a) (2010) (requiring that parents file a statement prohibiting retention of genetic material).

64. § 33.0112 (b).

65. *See* § 33.017 (c)(4) (providing that de–identified samples may be released for research purposes without the consent of the parent).

66. News Release, Tex. Dept. of State Health Servs., Statement: Newborn Screening Settlement (Dec. 22, 2009), *available at* http://www.dshs.state.tx.us/news/releases/20091222.shtm ("As a result of this settlement, DSHS will destroy all bloodspot cards received by the department before May 27, 2009, the date legislation expressly authorized the storage and specified uses of the samples."); *see also* Peggy Fikac, *State to Destroy 4 Million Newborn Blood Samples*, HOUSTON CHRON., Dec. 22, 2009 *available at* http://www.chron.com/disp/story.mpl/metropolitan/6782897.html ("The state will destroy an estimated 5.3 million blood samples legally collected from newborns but kept without parental consent under a federal lawsuit settlement announced Tuesday."); Nanci Wilson, *Government Taking Newborn DNA Samples: Many Ask Why They Are Saving the Samples*, KXAN AUSTIN NEWS, Nov. 24, 2009, *available at* http://www.kxan.com/dpp/health/government–taking–newborn–dna–samples (reporting that the lawsuit prompted a bill in the Texas legislature allowing the state to keep and use blood samples for research only if parents are informed and given the option of having their child's leftover samples destroyed after screening).

67. Update on the Texas litigation: A second lawsuit was filed on December 8, 2010 claiming that during the settlement negotiations on the first lawsuit, the Defendant, Texas Department of Health Services, "knowingly and deceptively" withheld certain information from the Plaintiffs. Specifically, the lawsuit alleges that the State lied about whether or not they had ever distributed or sold blood samples to other state or federal agencies or private companies. The Plaintiff's claim that the State gave newborn blood samples to private companies in exchange for a fee or various lab and testing equipment, and that the State also distributed blood samples to the Armed Forces Institute of Pathology, although the State had earlier denied doing so. Complaint, Higgins v. Texas Dept. of State Health Servs., No. 5:10–cv–00990 (W. D. Tex 2010) (on file with author). The case has been set for trial August 6, 2012.

B. Minnesota

Two apparently conflicting statutes are at the heart of the Minnesota lawsuit: (1) the State's Newborn Screening statute ("NBS statute")[68] and (2) the Minnesota Genetic Privacy Act ("GPA").[69] The NBS statute describes the Minnesota NBS Program, and allows the state to store indefinitely the bloodspots, but gives parents two alternative choices: (1) they may refuse the test, or (2) they may have the test but elect to have the blood samples and test records destroyed within 24 months of the testing.[70] The NBS statute does not require written parental informed consent; rather it is similar to the post–settlement Texas presumed consent statute that places the burden on the parent to object in writing.

In 2005, the Minnesota legislature directed the state health department to review the law governing the state's handling of genetic information. The health department recommended that the legislature be asked to create a definition for genetic information, and to give guidance on the collection, storage, use, and dissemination of genetic information not already addressed by existing law.[71] Subsequently, in 2006, the Minnesota legislature passed the GPA. The GPA defined "genetic information" as information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of... the individual's biological information or specimen...."[72] Germaine to the subsequent lawsuit, the GPA allowed a government entity to "collect genetic information only with the written informed consent of the individual," and provided that the information could be used, stored, and disseminated *only in accordance with the individual's written informed consent.*[73] In 2007, an administrative law judge report addressed certain proposed amendments to the newborn screening rules. The administrative court considered whether the GPA applied to genetic information collected under the NBS Program. [74] It found that, although the initial collection of the bloodspot is authorized by the NBS statute, the State had no statutory support for its practice of retaining the samples indefinitely without the consent of the parent, and that the opt–out nature of the initial screening

68. MINN. STAT. ANN. § 144.125 (2003).

69. MINN. STAT ANN §13.386 (West Supp. 2011).

70. MINN. STAT. ANN. § 144.125.

71. *See* Order Granting Motion to Dismiss at 5, Bearder v. Minn., No. 27–CV–09–5615 (4th Dist. Nov. 24, 2009), *available at* 2009 WL 5454446.

72. MINN. STAT. ANN. § 13.386 Subd. 1(a) (2011).

73. § 13.386 Subd. 3.

74. Proposed Amendments to Rules Governing Newborn Screening, Minnesota Rules, Chapter 4615, 19–21, No. 11–0900–17596–1 (Dept. of Health, March 23, 2007), *available at* http://www.oah.state.mn.us/aljBase/090017586.rr.htm.

was insufficient to support the State's practice.[75] Furthermore, the court found no statutory support for the State's dissemination of screening information to third party researchers.[76] The court concluded that the GPA did apply to the NBS rules, and the State's proposed amendments to the NBS Program were defective because they did not incorporate the requirements of the GPA.[77] The administrative findings were reviewed and confirmed by the Chief Administrative Law Judge[78]

On March 11, 2009, one day before the Texas lawsuit was filed, and after the encouraging administrative developments described above, seventeen parents representing nine families, filed suit in Minnesota state court. The Plaintiffs alleged that the State was in violation of its GPA because it used, indefinitely stored, and disseminated for outside research, the de–identified bloodspots and test information obtained pursuant to the State's NBS Program, without the written informed consent of the parents, as required by the GPA.[79] The State filed its motion to dismiss on the grounds that the GPA only protects genetic information. Bloodspots, it argued, were just blood, and not data or information obtained from the analysis of a biological specimen, as required by the GPA's definition of genetic information.[80] The Plaintiffs countered, asserting that only one purpose existed for the State's warehousing of the specimens—the future extraction of genetic information from the DNA located within the

75. *Id.* at 21; *see also id.* at 17 (finding that "parents are not informed that the Department will maintain the test results for an indefinite period of time; that the parents may decide later to request that the blood sample and test results be destroyed; or that the blood sample may be provided to outside institutions for research purposes").

76. *Id.* at 21. (finding that "[t]here is no express authorization in the newborn screening statute for the Department's current practice of retaining the information indefinitely without consent and permitting the information to be used without consent for purposes other than the detection, treatment, and follow–up of heritable and congenital disorders as contemplated by the newborn screening statute").

77. *Id.* at 19, (finding that "a parent or guardian must receive all of the information required by [the Generic Privacy Act] before the screening test is done and before the parent or guardian decide whether to "opt out" of the information retention scheme").

78. *See* Order Granting Motion to Dismiss at 6, Bearder v. Minn. No. 27–CV–09–5615 (Trial order Nov. 24, 2009), *available at* 2009 WL 5454446 (noting that the ALJ report was reviewed and confirmed by the Chief Administrative Law Judge).

79. *See* Plaintiff's Mem. of Law at 1–2, 6–7, 17, Bearder v. Minn., No. 27–CV–09–5615 (4th Dist 2009), *available at* 2009 WL 5427609.

80. *Id.* at n. 97 (referencing Def. Mem. of Law at p. 17, n. 13); *see also* MINN. STAT. ANN. § 13.386 Subd.1(West Supp 2011) (defining "genetic information" as "information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of: (1) the individual's biological information or specimen; or (2) the biological information or specimen of a person to whom the individual is related").

bloodspot; therefore, the mere storage of the bloodspots is constructively the use of "genetic information" as defined by the GPA.[81]

The state court judge agreed with the State, rejecting out of hand the reasoning of the administrative court, and granting the State's motion to dismiss the lawsuit. The court found that the screening samples were "not genetic information as defined in the GPA," but that even if they were, the "GPA did not supersede the provisions of the NBS Program."[82] The court reasoned that the Plaintiffs had the choice to request in writing that their samples not be stored indefinitely. The Court of Appeals affirmed the trial court, but the Minnesota Supreme Court granted the Plaintiffs Petition for Further Review on November 16, 2010.[83] At this writing, the case remains pending before the State's high court.

In both of the lawsuits described above, the state argued that the bloodspots and their accompanying information were coded to protect individual privacy, and no information would be released to outside researchers unless the research had been approved by an IRB, as required by federal regulations. What the lawsuits failed to consider, however, is whether the act of establishing a bloodspot research biobank was, in and of itself, medical research. Neither of the lawsuits described above considered whether the federal regulations for the protection of human research subjects, or federal guidance for establishing tissue repositories for research purposes, applied to NBS programs. Had they done so, they may have found that the law requires the written, informed consent of the parent before biobanking newborn blood for subsequent research purposes.

III. ARE THE FEDERAL PROTECTIONS FOR RESEARCH SUBJECTS RELEVANT TO STATE NBS PROGRAMS?

The federal protections for human research subjects are today codified in Title 45, Part 46 of the Code of Federal Regulations. Of prime importance is the recognition that the informed consent of research participants is absolutely essential.[84] To place in context the important role of informed consent in medical research, a brief history of these federal regulations is necessary.

The federal regulations governing research on human subjects grew out of a disturbing set of historical events, and at a time when medical research was at best secretive and unregulated, and, at worst, inhumane.

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81. Plaintiff's Mem. of Law, *supra* note 79 at 23.

82. Order Granting Motion to Dismiss, *supra* note 78.

83. Bearder v. Minn., 788 N.W.2d 144, 152 (Minn. Ct. App. 2010).

84. *See* 45 C.F.R. § 46.117 (2009) ("informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.").

The principle of informed consent developed in response to the atrocities committed by Nazi doctors and scientists under the guise of medical research during World War II, and the subsequent 1946 Nuremberg Military Tribunal that brought these war criminals to justice.[85] Part of the tribunal's decision included what has become known as the Nuremberg Code.[86] The Nuremberg Code was drafted during the War Crime Tribunals as a set of principles, or standards, for judging those physicians and scientists who had conducted medical experimentation on concentration camp prisoners.[87] The first principle of the Nuremberg Code is "[t]he voluntary consent of the human subject is absolutely essential."[88] Medical research practice in the United States, however, was surprisingly unchanged by the Nuremberg Trials and the ensuing world attention on the use of humans in medical research. The medical research community was hard pressed to believe that the rules arising out of Nazi atrocities could possibly relate to their research. It was not until 1966, when a highly controversial article by Dr. Henry K. Beecher provided twenty–two examples of unethical medical research published in leading medical journals, that the federal government focused on the need for regulation.[89] The public awareness of injustice and unethical research followed in 1972 when a reporter for the New York Times broke the story of the so–called Tuskegee Study, where it was revealed that the United States Public Health Service had conducted a forty–year long study of syphilis, using over 400 poor black sharecroppers from Alabama as subjects to study the progress of the disease.[90] The Government did not obtain consent from the men, nor were the men told that they had any disease other than "Bad Blood," although the government promised that the men would receive treatment for their

85. *See*, Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now, in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 227, 227–228 (George J. Annas & Michael A. Grodin eds., 1992).

86. *Id.*

87. Michael A. Grodin, *Historical Origins of the Nuremberg Code*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 121, 137–38 (George J. Annas & Michael A. Grodin eds., 1992).

88. Nuremberg Code, *in* 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER COUNTROL COUNCIL NO. 10, 181–82 (1949), *available at* http://ohsr.od.nih.gov/guidelines/nuremberg.html. This principle was modified in 1964 by the Declaration of Helsinki, which allows a legally authorized representative to consent for legally incompetent persons who are physically or mentally incapable of giving consent. Declaration of Helsinki: Ethical Principles for Medical research Involving Human Subjects,WORLD MEDICAL ASSOCIATION (1964), *available at* http://ohsr.od.nih.gov/guidelines/helsinki.html.

89. Henry K. Beecher, *Ethics in Clinical Research*, 274 NEW ENG. J. MED. 1354, 1355–1359 (1966).

90. Jean Heller, *Syphilis Victims in U.S. Study Went Untreated for 40 Years,* N.Y. TIMES, July 26, 1972, at 1,8.

condition.[91] The men did not receive any treatment and, most shocking, even after penicillin therapy became available to treat the disease, these men were not offered the treatment. Rather, the goal of the government program was to follow the men to their deaths, and through autopsy, continue research on syphilis.[92]

Following this revelation, the Food and Drug Administration ("FDA") and the National Institutes of Health ("NIH") developed internal guidelines providing rudimentary subject protections that were codified as federal regulations in 1974.[93] At the same time, the newly formed National Commission for the Protection of Human Subjects of Biomedical Research and Behavioral Research ("National Commission") was given the task of identifying the ethical principles underlying biomedical research involving human subjects and instructed to develop federal guidelines.[94] Among the seventeen reports produced by the National Commission was the Belmont Report. This report provided a framework for solving the ethical problems that arise in human subject research, and it is the Belmont Report that is the basis for the current federal regulations governing the protection of human research subjects.

The Belmont Report identified and explained three fundamental ethical principles necessary for the protection of human subjects in medical experimentation: (1) respect for persons; (2) beneficence; and (3) justice.[95] The requirement for informed consent arises out of the ethical principle of respect for persons. According to the Belmont Report:

> Respect for persons incorporates at least two ethical convictions, first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.[96]

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91. JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 5 (expanded ed. 1993).

92. *Id.* at 138.

93. Harold Y. Vanderpool, *Introduction and Overview: Ethics, Historical Case Studies and the Research Enterprise, in* THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS FACING THE 21ST CENTURY 1, 10 (Harold Y. Vanderpool ed. 1996).

94. *See* William J. Winslade & Todd L. Krause, *The Nuremberg Code Turns Fifty, in* ETHICS CODES IN MEDICINE: FOUNDATIONS AND ACHIEVEMENTS OF CODIFICATION SINCE 1947, 150 (Ulrigh Trohler & Stella Reiter–Theil eds., 1996).

95. *See* The Belmont Report: Ethical Principles & Guidelines for Research Involving Human Subjects, 44 Fed. Reg. 23,192, 23,193–194 (Apr. 18, 1979), *available at* http://www.hhs.gov/ohrp/policy/belmont.html.

96. *Id.* at 23,193.

The Belmont Report stressed the importance of distinguishing between medical practice and medical research, warning that the line between practice and research is blurred because often both occur together.[97] Practice is designed for the well–being of the patient, and the physician diagnoses and treats her patient accordance with methods that have a reasonable expectation of success. Research, on the other hand, is designed to test a theory, or hypothesis, that will, hopefully, benefit society in the future.[98] Thus, the term "subject" is used to denote one who participates in research, as opposed to the "patient" who is treated for an illness.[99]

In the context of newborn screening, the original purpose of NBS programs was only to discover, diagnose, and treat the baby born with a heritable disease—a process that was solely for the benefit of the baby. On the other hand, a newborn who gives blood for medical research purposes has no such expectation of individual benefit. The bloodspot will be biobanked and disseminated in the future to investigators for genetic research that will one day, hopefully, benefit society at large. The newborn is, at the same time, the "patient" being screened for heritable diseases, and the "subject" of genetic research. To the extent that the newborn is a "research subject," as discussed *infra*,[100] the ethical precepts as expressed in the Belmont Report, and today in the federal regulations, would require written informed consent prior to bloodspot collection.

A. Are State Newborn Screening Programs "Conducted or Supported" by a Federal Department or Agency?

The Federal Regulations for Human Subject Protection,[101] also known as the Common Rule,[102] apply only to "research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency."[103] State NBS programs are regulated by state public

97. *Id.*

98. *Id.* Medical ethicist Jay Katz notes that it is "imperative to view clinical research as a distinct category, sharply delineated from clinical practice." Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L. J. 7, 17 (1993).

99. Katz, *supra* note 98 at 17 (noting that it is "imperative to view clinical research as a distinct category, sharply delineated from clinical practice").

100. *See infra* Part III.B.

101. Protection of Human Research Subjects, 45 C.F.R. §§ 46.101-46.505 (2009).

102. Seventeen federal agencies responsible for funding or engaged in research have adopted verbatim the human subject protections set forth in the Code of Federal Regulations. Russell Korobkin, *Buying and Selling Human Tissues for Stem Cell Research*, 49 ARIZ. L. REV. 45, 52 n.37 (2007). Thus, it is called the Common Rule. Research that is subject to the Common Rule must be reviewed by an Institutional Review Board (IRB). The IRB is responsible for assuring that proper informed consent is obtained from the subjects who will participate in the research. 45 C.F.R. §§ 46.111 (a)(4)–(5) (2009).

103. 45 C.F.R. § 46.101 (a).

health departments. As such, they have not traditionally been viewed as subject to the federal regulations for the protection of human subjects. The federal imprint has become significantly more visible, however, with the increasing state practice of storage and use of newborn screening samples for genetic research. In a general sense, federal support is also evident in a recent major national guidance document aimed at creating uniformity in the storage and research use of newborn bloodspots.[104] Applying the federal human subject protections to state NBS programs would assure that voluntary, informed consent is obtained from all parents before their child's bloodspot is used for research that is not directly related to the screening program.[105]

The federal government's regulations that protect human subjects ought to apply to state NBS programs because the federal government, primarily through the Department of Health and Human Services ("DHHS"), is inextricably intertwined with state NBS programs through its direct financing of these programs, and indirectly through DHHS, NIH, and other federal programs. For example, fully one–third of all births are financed by Medicaid, the federal–state health insurance program for eligible low–income individuals, and newborn screening is a Medicaid covered service.[106] State laboratories that analyze newborn bloodspots must meet the regulatory requirements established by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").[107] If state laboratories fail to meet CLIA requirements, they are subject to denial of Medicaid payments.[108] The Health Resources and Services Administration ("HRSA"), a federal agency that collects information on state NBS

104. HEALTH RES. AND SERVS. ADMIN., SEC'YS ADVISORY COMM. ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN, CONSIDERATIONS AND RECOMMENDATIONS FOR NAT'L GUIDANCE REGARDING THE RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT SPECIMENS AFTER NEWBORN SCREENING 33 (2010), *available at* http://www.hrsa.gov/heritabledisorderscommittee/RBSBriefingPaperFINALDraft42310.pdf.

105. The Federalwide Assurance (FWA). All institutions engaged in non–exempt human subject research that is conducted or supported by any HHS Agency must be covered by an Office for Human Research Protection (OHRP) approved assurance of compliance, called a Federal Wide Assurance. Under an FWA, an institution (or state) commits that it will comply with the federal human subject requirements, including informed consent requirements, as set forth in 45 C.F.R. Part 46. The FWA also means that other federal agencies may rely on the FWA for the research they conduct or support. *See generally*, Federalwide Assurance for the Protection of Human Subjects, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html.

106. U.S. GOVT ACCOUNTABILITY OFFICE, GA– 03–449, NEWBORN SCREENING: CHARACTERISTICS OF STATE PROGRAMS 5–6 (2003), ("The Centers for Medicare & Medicaid Services' (CMS) involvement in newborn screening relates to its Medicaid and CLIA programs. . . . Medicaid finances services for one in three births each year.").

107. *Id.* at 3.

108. *Id.* at 7.

programs, offers block grants to states to support their newborn screening services.[109] The Newborn Screening Saves Lives Act of 2007 orders the creation of a National Contingency Plan for Newborn Screening to assure program continuation in the event of a public health emergency.[110] The Contingency Plan is to ensure continuation of the NBS Program, as well as "carrying out other activities determined appropriate by the Secretary," which could include subsequent genetic research programs.[111] The Newborn Screening Saves Lives Act of 2007 authorizes over $5,000,000 per year to assist "laboratories involved in screening newborns and children for heritable disorder" for various program integrity purposes.[112] Moreover, the newly established Hunter Kelly Newborn Screening Research Program authorizes the government to expand genetic research in newborn screening, to develop new screening technologies, expand the number of conditions for which screening tests are available, and "other genetic, metabolic, hormonal and or functional conditions that can be detected through newborn screening for which treatment is not yet available."[113] Entities receiving funding through the program must assure the government that they will "work in consultation with the appropriate State departments of health.[114] In conducting the genetic research described above, the newborn bloodspot repositories are indispensable. The federal protections for human subjects ought to apply, given that at least a portion of the federal money supporting NBS Programs is used to collect, analyze, and store newborn bloodspots for future research purposes.

Moreover, the government has historically supported state NBS programs indirectly through policy guidance. In 1985, HRSA funded development of the Council of Regional Networks for Genetic Services ("CORN") to centralize information concerning the public health aspects of genetic services.[115] In 1996, CORN's Newborn Screening Committee published *Guidelines for the Retention, Storage, and Use of Residual Dried Blood Spot Samples after Newborn Screening Analysis: Statement of the Council of Regional Networks for Genetic Services.*[116] The stated purpose

109. *Id.* at 3,5. Federal grants include the Maternal and Child Health Services Block Grant for newborn screening services support. *Id.* at 5.

110. Newborn Screening Saves Lives Act of 2007, Pub. L. No.110–204, sec. 7, § 1115, 122 Stat. 705, 711(2008)

111. *Id.* at sec. 7, § 1115(b)(8).

112. *Id.* at sec. 6, §1113 (authorizing over $5,000,000 for fiscal years 2009 through 2013 to newborn screening laboratories for quality assurance and performance evaluation).

113. *Id.* at sec. 7, § 1116(a)(1).

114. *Id.* at sec. 7, § 1116 (b).

115. U.S. GOVT ACCOUNTABILITY OFFICE, *supra* note 106, at 5..

116. Bradford L. Therrell et al., *Guidelines for the Retention, Storage, and Use of Residual Dried Blood Spot Samples After Newborn Screening Analysis: Statement of the Council of Regional Networks for Genetic Services*, 57 BIOCHEMICAL AND MOLECULAR MED. 116 (1996).

of the paper was "to provide scientific information for policy development by state health departments."[117] In 1999, CORN was replaced by the National Newborn Screening and Genetics Resource Center ("The Resource Center"), a cooperative agreement between HRSA's Maternal and Child Health Bureau and the University of Texas Health Science Center Department of Pediatrics.[118] The government's most recent endeavor to shape state newborn screening policy is its 2010 briefing paper produced by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, titled "Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening" ("2010 SACHDNC Draft National Guidance").[119]

Given that the federal government has directly and indirectly supported state newborn screening programs, as described in detail above, the federal human subject protections ought to apply to genetic research arising directly from those programs.

B. Do NBS Programs Involve Human Subject Research?

The federal regulations apply only to research conducted on human subjects. The federal regulations define research as "a systematic investigation . . . designed to develop or contribute to generalizable knowledge."[120] Research using newborn DNA, then, is designed to advance genetic research so that society as a whole may benefit in the future, and not for the individual benefit of the baby who supplies the blood. Thus, collection of newborn bloodspots for research purposes is "research" under the federal regulatory definition.

Moreover, the federal regulations apply only if the research involves "human subjects." The Minnesota state court viewed a newborn bloodspot as merely a biological sample, and not as human being's identifiable genetic information deserving of legal protection. In both lawsuits described above, the states argued that because the sample and test results were de-identified before being disseminated for outside research, they could not reasonably be connected to any individual; thus, "human subjects" were not involved, and parental consent was not required. According to the federal regulations, however, a "human subject" is "a living individual about whom an investigator (whether professional or

117. *Id.* at 116.

118. U.S. GOVT ACCOUNTABILITY OFFICE, *supra* note 106, at 6; *see also* The National Newborn Screening and Genetics Resource Center, http://genes-r-us.uthscsa.edu/ (last visited May 25, 2011).

119. HEALTH RES. AND SERVS. ADMIN., *supra* note 104, at ii.

120. Protection of Human Research Subjects, 45 C.F.R. § 46.102(d) (2009)..

student) conducting research obtains (1) data through intervention or interacting with the individual, or (2) identifiable private information.[121] And, "intervention" includes physical procedures by which data are gathered, such as venipuncture for blood collection. [122] Thus, the process of obtaining the blood from the newborn, and attaching that bloodspot to the Guthrie card, may meet the federal definition of research on a "human subject." The physician interacts with the newborn to obtain the blood containing the baby's valuable DNA, and the Guthrie card contains identifiable private information about the baby and the mother that will be biobanked for future genetic research purposes. In essence, within state NBS programs, the newborn is at the same time, a "patient" being screened for genetic diseases for the baby's personal benefit, and a "human subject" involved in research. Given the basic premise that the baby's blood is drawn for the dual purposes of screening and medical research, the federal regulations regarding the protection of human subjects ought to be observed at, or prior to, the point of blood collection. The written, informed consent of the subject—here, the parent or guardian of the newborn, ought to be obtained.

C. Does Newborn Bloodspot Biobanking Qualify for an Exemption or a Waiver from the Federal Regulations?

Certain categories of research activities are exempt from federal regulations, and do not require informed consent. One exempt category is research conducted on already–existing diagnostic or pathological specimens collected for clinical care (and not research) purposes, if the information is recorded such that "subjects cannot be identified, directly or through identifiers linked to the subjects." [123] In this vein, the Minnesota trial court opinion characterized the newborn bloodspots as mere "biological samples," and found that parental informed consent was unnecessary because the samples were de–identified prior to being disseminated for research.[124]

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121. 45 C.F.R. § 46.102(f).

122. *Id.* "Venipuncture" is the "surgical puncture of a vein." MILLER–KEANE ENCYCLOPEDIA & DICTIONARY OF MEDICINE, NURSING, & ALLIED HEALTH 1597 (5th ed.1992).

123. 45 C.F.R. § 46.101 (b)(4) (exempting from federal policy: "Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.");*see also* Katherine Drabiak–Syed, *State Codification of Federal Regulatory Ambiguities in Biobanking and Genetic Research*,30 J. LEGAL MED. 299, 300 (2009) (noting that anonymous samples with no identifying information are not covered by the federal regulations).

124. Order Granting Motion to Dismiss, *supra* note 71, at 4, 10.

The federal regulatory exemption should not apply to NBS sample collection for three reasons. First, this exemption presupposes that the samples are collected initially in the course of diagnosis or treatment of a known or suspected medical condition, and that, for subsequent research purposes, they are already–existing pathological specimens. To the contrary, the bloodspots are collected as part of a population–wide screening *and research* program. The basic premise of this article is that, today, and increasingly in the future, newborn screening has two distinct purposes, one of which is to establish a bloodspot biobank for use in conducting future genetic research. A 2004 OHRP guidance document defines "existing" as "existing before the research is proposed to an institutional official or the IRB . . . ."[125] Although no specific research protocol exists at the time of bloodspot collection, one purpose of bloodspot collection and storage is for *future* genetic research.[126] Viewed in this light, it seems disingenuous to claim that these biobanked bloodspots were "already existing" clinical specimens entitled to exemption from informed consent requirements. Second, the federal exemption applies only to specimens that "cannot be identified, directly or through identifiers linked to the subjects."[127] The bloodspot, however, is affixed to the Guthrie card, which contains the baby's and mother's identifying information. According to a 2002 study, all except two of the 36 state NBS programs studied stored their newborn bloodspots with the identifying information present.[128] And, even though the samples are coded (de–identified) before being disseminated to outside researchers, they are not anonymous, and can be re–identified if necessary. Third, the statutory exemption was enacted long before the explosion of scientific advances in genotyping and genetic sequencing wrought by the Human Genome Project.[129] In that respect, the general application of the exemption to biobanks is outdated.[130]

Finally, newborn bloodspot collection and storage would not be eligible for a waiver of informed consent under the federal regulations. An IRB may waive informed consent requirements for certain low–risk

125. OFF. FOR HUMAN RESEARCH PROTECTION, HUMAN SUBJECT REGULATIONS DECISION CHARTS Chart 5 (Sept. 24, 2004), *available at* http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html.

126. Mark A. Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J.L. MED. & ETHICS 89, 89 (2005).

127. 45 C.F.R. §46.101 (b)(4).

128. Kenneth D. Mandl et al., *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269, 271 (2002).

129. Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 24 (2005) (quoting Charles MacKay and Gerald S. Schatz, The Unfinished Research Agenda, Address to the Nat'l Insts. of Health Inter–Ins. Bioethics Internet Group (June 7, 2004)).

130. *See* Andrews, *supra* note 129, at 24 (noting that the federal statutory exemption "was adopted long before the advent of widespread genotyping and genetic sequencing").

research if the research cannot be done unless the informed consent requirement is waived. In order for a researcher to obtain a waiver, she must show that "the research could not practicably be carried out without the waiver."[131] For example, an IRB may grant a waiver for a large–scale epidemiological study using medical records spanning a significant time period. [132] Obtaining informed consent from all of the patients under these circumstances would be very difficult if not impossible to do. In the context of newborn screening, however, a physician–patient relationship already exists between the physician and the mother–to–be, and it is typically the physician that is responsible for obtaining the bloodspot for screening and research; thus, no barrier exists that would prevent the physician from also obtaining proper informed consent for bloodspot storage and future research. To the contrary, it is quite "practicable" for the provider to obtain informed consent from the mother–to–be.

Even in cases of exempt research, or where the research may be eligible for a waiver, many institutions still obtain consent from donors whenever possible.[133] This is likely so because institutions are aware that scientific advances in the field of genetics have left the public concerned, and even suspicious, about the nonconsensual use of their genetic information. Genetics professor and scholar, Ellen Wright Clayton, in her article *Patients and Biobanks*, notes that health care institutions recognize that:

> [N]on–disclosure and lack of oversight are risky in terms of public perception. It is hardly as if the American public is universally enthusiastic about its hospitals and clinicians. The health care system is under fire from a number of directions, from concerns that too many people are falling through the cracks or being bankrupted to allegations of fiscal mismanagement, fraud, and poor quality of care. As part of this sea of concerns, health care institutions know that at least some patients are concerned about how

131. 45 C.F.R. § 46.116(d) (providing that an IRB may either waive or alter the informed consent requirement if "(1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation") *See also* Sandra J. Carnahan, *Promoting Medical Research Without Sacrificing Patient Autonomy: Legal and Ethical Issues Raised by the Waiver of Informed Consent for Emergency Research*, 52 OKLA. L. REV. 565, 567 (1999).

132. CARL H. COLEMAN ET AL., THE ETHICS AND REGULATIONS OF RESEARCH WITH HUMAN SUBJECTS 313 (2005).

133. *See* Ellen Wright Clayton, *Patients and Biobanks*, 51 VILL. L. REV. 793, 796–97 (2006) (noting that even projects that are technically exempt under OHRP guidance and other legal regulations, many institutions still obtain consent).

> information about them and specimens from them are used.[134]

Given that the newborn bloodspot is collected for the dual purpose of diagnosis and research, and that it is linked with identifying information when it is biobanked, federal regulations, and federal guidance for establishing research repositories would require parental informed consent. Only written informed consent can fully protect research subjects, and maintain the public trust in NBS programs.

IV. INFORMED CONSENT FOR PROSPECTIVE RESEARCH

Human tissue repositories collect, store, and distribute human tissue and other biological material for research purposes. If the biological material in the repository contains at least traces of DNA or RNA that would allow genetic analysis, it is typically termed a "biobank," [135] although the terms "repository" and "biobank" are often used interchangeably. When biobanks, such as the newborn bloodspot biobanks, are established for future, long–term research use, they are known as "prospective" biobanks. One difficulty with prospective biobanks is that, at the time samples are collected, it is difficult to anticipate the specific future use of the samples; thus, informed consent policy for biobank collection is difficult to formulate.[136]

The 2010 SACHDNC Draft National Guidance recognizes that "[s]ome form of consent or formal IRB waiver of consent appears to be necessary if newborn screening specimens are to be placed into a repository for research purposes since *creation of a research repository is, in and of itself, research.*"[137] The Office for Human Research Protection ("OHRP"), formerly the Office for Protection from Research Risks, has published guidance for the collection, storage, and research use of stored data or tissues, and provides a possible model for newborn blood spot biobanks:

> Operation of the Repository and its data management center should be subject to oversight by an Institutional Review Board (IRB). The IRB should review and approve a protocol specifying the conditions under which data and specimens *may be accepted* and shared, and ensuring adequate provisions to protect the privacy of subjects and

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134. *Id.* at 802.

135. *See* Bernice S. Elger & Arthur L. Caplan, *Consent and Anonymization in Research Involving Biobanks* 7 EMBO REPORTS 661, 661 (2006) (noting that the term "biobank" often refers to "any collection of human biological material . . . that contains at least traces of DNA or RNA that would allow genetic analysis").

136. *See id.* at 663.

137. HEALTH RES. AND SERVS. ADMIN., *supra* note 104, at 12–13 (emphasis added).

> maintain the confidentiality of data. *The IRB should also review and approve a sample collection protocol and informed consent document* for distribution to tissue collectors and their local IRBs.[138]

The above model would be appropriate for establishing state research repositories for newborn bloodspots, including IRB review and approval of an informed consent document to be given to the parent a reasonable time before birth. According to federal guidelines, the tissue collector is required to obtain the informed consent of the donor when tissue is collected for a research repository.[139] Written informed consent should be obtained in accordance with the Common Rule,[140] and should clearly describe, as specifically as possible, the types of research to be conducted, operation of the repository, the conditions under which samples will be released to investigators, and procedures for protecting the subject's privacy and maintaining confidentiality. [141]

Asking a parent to consent to the use of her child's bloodspot for future research is ethically problematic, given that an approved research protocol does not yet exist. Studies may emerge in the future that cannot be anticipated at present. Thus, the parental consent would not include specific research details. Parents can, however, be asked to consent to a particular class of future research if its potential risks and benefits are explained.[142] Bioethicists Bernice Elger and Arthur Caplan describe what they dub the "European solution," for obtaining consent from subjects for the future research use of their biological materials. They identify three characteristics of informed consent for European biobanks: (1) a general consent to future research use, (2) subsequent approval of the specific research by an ethics committee, and (3) the subject's right to withdraw his or her biological

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138. OFF. FOR HUMAN RESEARCH PROTECTION, *Issues to Consider in the Research Use of Stored Data or Tissues* (Nov. 7, 1997), http://www.hhs.gov/ohrp/policy/reposit.html (emphasis added).

139. 45 C.F.R. § 46.116 (2009).

140. *See* 45 C.F.R. § 46.116 (setting forth the general requirements for informed consent). Consent must be obtained only under circumstances that allow a prospective subject sufficient opportunity to consider whether or not to participate in the research. *Id.* The elements of informed consent include the following: the subject must be told that the study involves research and what is the purpose of the research; the subject must be told of reasonably foreseeable risks or discomforts, as well as any benefit to the subject or others; and the informed consent form must include a statement that participation is voluntary, and that the subject may decide at any time not to continue participation in the research. *Id.* Subjects also should be given additional information if it would "meaningfully add to the protection of the rights and welfare of subjects." 45 C.F.R. § 46.109(b).

141. OFF. FOR HUMAN RESEARCH PROTECTION, *supra* note 138.

142. NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 49 (1999).

sample from the research at any time.[143] This general consent, also called blanket consent, would be particularly suitable in the newborn screening context. One such model is the Michigan BioTrust for Health. Effective October 1, 2010, hospitals and midwives will give parents of newborns the option of signing a consent form if they want their baby's bloodspot sample to be available for medical research. [144] Before signing the consent form, the parent is provided with a booklet containing detailed information about the BioTrust program. [145] The consent form explains that participation in research is voluntary, that a parent may change her mind at any time, that when the child is 18, he or she may ask to have his or her bloodspot removed, and that there is no penalty for choosing not to consent to research on the bloodspot.[146]

Taking blanket consent one step further, however, parents could be allowed to express their preferences for future research, and to limit that research in ways that are important to them.[147] For example, a parent may consent to all future research except that relating to cloning, or perhaps mental health.[148] A general consent could also include consent to specimen collection, specimen storage, and subsequent specimen transfer to investigators or other facilities.[149]

Newborn bloodspots will become increasingly essential for genetic research, and in most cases be disseminated post–collection to outside researchers without additional parental consent if the bloodspots are de–identified. Thus, it is essential that parents be fully informed about the general nature of future research—that scientists will use their baby's DNA to conduct *genetic* studies, as opposed to general medical research.[150]

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143. Elger & Caplan, *supra* note 133, at 663; *see also* Ellen Wright Clayton, *Informed Consent and Biobanks*, 33 J. L. MED. & ETHICS 15, 19–20 (2005).

144. MICH. DEPT. OF COMMUNITY HEALTH, Michigan BioTrust for Health–Consent Options, http://www.michigan.gov/mdch/0,1607,7–132–2942_4911_4916–244016—,00.html (last visited May 25, 2011).

145. *See* MICH. BIOTRUST FOR HEALTH, *After Newborn Screening: Facts About Using Your Child's Bloodspots for Research* (2010), *available at* http://www.michigan.gov/documents/mdch/Biotrust_Book_327197_7.pdf (explaining that blood spots will be stored and used for medical and public health research by way of parental permission).

146. MICH. DEPT. OF COMMUNITY HEALTH, Michigan BioTrust Consent Form, *available at* http://www.phla.info/Michigan%20Consent_Form_Proof1.pdf (Dec. 2008).

147. *See* NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 142, at 49 (stating that "[a]llowing individuals to express their preferences for future research is consistent with respecting persons").

148. Drabiak–Syed, *supra* note 123, at 327.

149. *Id.* at 326–327.

150. *See* TEX. HEALTH & SAFETY CODE ANN. § 33.017(c)(4) (West 2009) (providing that de–identified information "may be released without consent if the disclosure is for: . . . (4) research purposes, provided that the disclosure is approved by an institutional review board or privacy board of the department").

Parents ought also to be informed that, while many steps are taken to protect their child's privacy, and to ensure the security of their child's genetic information, complete privacy cannot be guaranteed.[151]

The mother's physician is the logical person to discuss with her the disposition of the newborn's post–screening bloodspots. Obtaining informed consent in the clinical setting, however, can be stressful, especially when the decisions to be made do not involve the mother or baby's clinical care.[152] The consent process should take place at a time when the mother–to–be and her physician can comfortably communicate—certainly not when the birth is imminent. In these circumstances, the National Bioethics Advisory Commission has recommended that informed consent to the research use of biological materials should be obtained separately from informed consent to clinical procedures. [153]

V. SECURING THE PUBLIC'S TRUST: THE FALLACY OF PRESUMED CONSENT

States risk loss of the public trust in their well–established NBS programs if they do not obtain the written, informed consent of parents before taking bloodspots for the dual purposes of screening and research. Where research occurs without parental consent, or even within a presumed consent system, parental confusion and misunderstanding could lead to a general distrust of essential state NBS programs—an undesirable and potentially disastrous result. The 2010 SACHDNC Draft National Guidance recognizes the importance of securing the public trust, and urges that "some indication of the parents' awareness and willingness to participate should exist . . . ."[154] The 2010 SACHDNC Draft National Guidance leaves the individual states to deal with the particular form of informed consent. This section argues that a presumed consent system is not appropriate for newborn screening research, and that nothing short of the parent's written and fully informed consent will secure the public trust.

Media headlines reflect public dismay upon discovery that states had been storing newborn bloodspots for genetic research: "The Government Has Your Baby's DNA;"[155] Texas is Selling Your Baby's Blood;"[156]

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151. *See* Leslie E. Wolf, *Advancing Research on Stored Biological Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J.L. SCI. & TECH. 99, 133 (2010) (discussing recent scientific developments that question whether DNA can be de–identified).

152. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 142, at 63–64 (stating that "stress level may be high in clinical settings, rendering them not conducive to a consent process that involves making complex choices regarding issues that are not related directly to clinical care and that involve speculation about the distant future").

153. *Id.* at 64.

154. HEALTH RES. AND SERVS. ADMIN., *supra* note 104, at 19–20.

155. Elizabeth Cohen, *The Government has Your Baby's DNA*, CNN, Feb. 3, 2010, http://www.cnn.com/2010/HEALTH/02/04/baby.dna.government/index.hmtl?hpt=C2

"Parents Outraged at Warehousing of DNA Saved From Newborn Baby Screening Programs and Used for Clinical Laboratory Testing;"[157] Suit Possible Over Baby DNA Sent To Military Lab For National Database;"[158] "State Agency Swaps Babies' Blood For Supplies;"[159] "Baby's Blood Samples Used to Create DNA Database;"[160] "Newborn Blood Used to Build Secret Database;"[161] and so forth.

Most states have not yet incorporated into their NBS Programs any process for informing parents of procedures regarding the storage and genetic research use of their child's bloodspot. In response to the 2010 SACHDNC Draft National Guidance, some states may now be considering instituting a presumed consent system. Texas adopted a presumed consent system in 2009 in response to the litigation addressed herein,[162] and a similar system is in place in Minnesota.[163] But presumed consent systems are inadequate for genetic research because they are based on faulty premise.

Presumed consent in the newborn screening context is based on the principle that essentially all parents would want to contribute to genetic research and, if asked, would choose to do so. As the argument goes, a presumed consent system that makes research participation the default choice merely makes it easier for parents to do what they already wish to do. This presumption, however, is inaccurate in several respects. General support for genetic research does not necessarily equate to a willingness to donate the blood of one's child to that purpose. Robert Weir and Robert Olick, in their book "The Stored Tissue Issue," write that a significant

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156. Paul Knight, *Texas is Selling Your Baby's Blood Without Consent, Lawsuit Says*, HOUSTON PRESS, Dec. 10, 2010, http://blogs.houstonpress.com/hairballs/2010/12/babys_blood_lawsuit.php.

157. K. Branz, *Parents Outraged at Warehousing of DNA Saved From Newborn Baby Screening Programs and Used for Clinical Laboratory Testing*, DARK DAILY, Mar. 5, 2010, http://www.darkdaily.com/parents-outraged-at-warehousing-of-dna-saved-from-newborn-baby-screening-programs-and-used-for-clinical-laboratory-testing.

158. Mary Ann Roser, *Suit Possible Over Baby DNA Sent to Military Lab for National Database*, STATEMAN.COM, Feb. 22, 2010, http://www.statesman.com/news/texass-politics/suit-possible-over-baby-sent-to-military-268714.html.

159. Mary Ann Roser, *State Agency Swaps Babies' Blood for Supplies: Companies Use Blood to Produce and Test Equipment*, , STATEMAN.COM, May 10, 2010, http://www.statesman.com/news/texas-politics/state-agency-swaps-babies-blood-for-supplies-678302.html.

160. Olivia Conroy, *Babies' Blood Samples Used to Create DNA Database*, TOP NEWS, May 24, 2010, http://topnews.us/content/220465-babies-blood-samples-used-create-dna-database.

161. Ewen Callaway, *Newborns' Blood Used to Build Secret DNA Database*, NEW SCIENTIST, Feb. 24, 2010, http://www.newscientist.com/blogs/shortsharpscience/2010/02/ewen-callaway-reportertexas-he.html

162. TEX. HEALTH & SAFETY CODE ANN. § 33.0111 (West 2009).

163. MINN. STAT. ANN. § 144.125 Subd. 3 (2011).

number of Americans are not comfortable with the use of their personal blood and tissues for scientific studies, even though they generally support biomedical research.[164] In support of their conclusion, these authors chronicle several studies surveying public opinion on this issue.[165] In a University of Iowa Pilot Study of 93 patients, 73% stated they would be "very" or "somewhat bothered" if their post–diagnostic tissues were used for research without first obtaining their consent.[166] In another study, 10 to 15 participants in each of sixteen focus groups were asked to review a simple Model Consent Form for Biological Tissue Banking, which might be given to a patient prior to surgery.[167] After reviewing the form, participants expressed suspicions and concerns on several fronts, including privacy concerns, the type of research that would be done, the possible profit motives of the researchers, and their "overwhelming" belief that patients should be given the form several days before the surgery to allow time for reflection or to change their mind.[168] And in the largest public opinion study, the Center for Disease Control (CDC) researchers analyzed data from 2,621 participants regarding blood donation and storage for genetics research.[169] The data showed that 10% of the participants would donate blood but would not want it stored for long–term research, 27% were not willing to donate blood for research even if their privacy could be assured, and 21% would not, under any circumstances, donate blood, or have it stored for research. [170]

Some groups may find genetic research to be objectionable for religious or cultural reasons. Geneticist and Hopi Indian Frank Dukepoo has expressed Native American concerns with genetic research relating to

164. ROBERT F. WEIR & ROBERT S. OLICK, THE STORED TISSUE ISSUE 26 (2004) ("[T]here is a growing body of evidence suggesting that a significant portion of the American public is not convinced they want their tissues to be used for scientific studies. Persons surveyed usually support biomedical research and value the achievements gained through research, but many remain unconvinced that research studies on banked tissue samples is a trustworthy enterprise that they should personally support with samples of their own blood, cheek cells, urine, skin, and other tissues.").

165. *See id.* at 27–31 (summarizing a University of Iowa Pilot study, a National Action Plan on breast cancer study, a 1998–1999 National Bioethics Advisory Committee study, and a 2001 Georgetown University/University of Maryland study).

166. *Id.* at 27.

167. *Id.*

168. *Id.* at 27–28.

169. *Id.* at 30. The CDC study, published in 2001, was based on data collected from the 1998 American Healthstyles annual market research survey. *Id.* The 1998 version of the survey solicited participant responses to several genetics statements from which the percentage statistics are drawn. *Id.*

170. *Id.* at 30–31 (noting that CDC investigators were concerned with the study results because they knew that the future of genetic research "depends on public attitudes toward the donation and long–term storage of blood samples").

cloning, gene patenting, "immortalized" cell lines, and commercialization.[171] Some may not want to have their biological materials used in contraceptive research, mental health studies, or studies of ethnicity and criminal behavior or violence. Information about an infant's genetic variation may be of substantial interest to researchers, health insurers, and marketers, and some persons may be concerned that their samples will be sold to for–profit commercial enterprises.[172] Still others may be concerned that the indefinite storage of their blood and identifiable medical information, if published, may lead to discrimination in health insurance and employment, or create stigmatization.[173] Twila Brase, public health nurse and President of the advocacy group, Citizen's Council for Health Freedom, has expressed concern that newborn bloodspot research could result in a genetic profile that would be used for eugenic purposes.[174]

In a recent and particularly relevant study, researchers assessed the attitudes of 1508 parents regarding storage and use of newborn bloodspots for genetic research.[175] Not surprisingly, 55.7% of the 1508 parents surveyed were "very unwilling" to permit research on their child's bloodspot without their permission.[176] Only 11.3% were "very willing" to permit use of the NBS sample without their permission.[177] Even when parental permission was sought, 23.8% remained either "very unwilling," or "somewhat unwilling" to permit research use of the samples.[178] Another study examined women's willingness to enroll their children in a hypothetical pediatric biobank.[179] The research revealed significant misconceptions about what participation in a biobank would mean, and

171. *Sensitivities and Concerns of Research in Native American Communities: Hearing Before the Nat'l Bioethics Advisory Comm'n*, 105th Cong. 25–27 (1998) (statement of Frank Dukepoo), *available at* http://govinfo.library.unt.edu/nbac/transcripts/jul98/day1.pdf.

172. *See* NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 142, at 49 (generally describing "objectionable, unacceptable, or questionable research"); *see also* Kenneth D. Mandl et al., *supra* note 128, at 269 (introducing reports from a study defining "current practice among newborn screening programs").

173. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 142, at 44–45.

174. Twila Brase, *Newborn Genetic Screening, the New Eugenics? The Case for Informed Consent Requirements for Genetic Testing, Baby DNA Storage and Genetic Research*, CCHC REPORT, Apr. 2009, at 10.

175. Beth A. Tarini, et al., *Not Without My Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research*, 13 PUB. HEALTH GENOMICS 1, 2–32, (2009), *available at* http://www.cchfreedom.org/pdf/tarini_biobanking%20paper_parent%20attitudes.pdf.

176. *Id.* at 3–4.

177. *Id.* at 3.

178. *Id.*

179. *See* Alon B. Neidich, et al., *Empirical Data About Women's Attitudes Towards a Hypothetical Pediatric Biobank*, 146 AM. J. MED. GENETICS 297, 298 (2008), *available at* http://www3.interscience.wiley.com/journal/117888916/abstract?CRETRY=1&SRETRY=0 (surveying women eighteen years of age or older and within seventy–two hours of child delivery at the University of Chicago Hospitals).

misunderstanding about who would have access to the information and how information would be protected.[180] 26% of the 207 women polled did not feel that they had enough information to decide whether or not to enroll their child.[181]

Public officials should not attempt to bypass parental consent in an effort to avoid their refusal to participate in genetic research. Bypassing parental consent serves only to fuel the flames of government mistrust, reinforce common misconceptions, and confirm society's deepest fears about genetic research. Presumed consent is the ideological opposite of written informed consent. In his article *Presumed Consent to Organ Donation: Its Rise and Fall in the United States*, David Orentlicher reviews America's failed forty–year–long limited experiment with presumed consent statutes designed to increase the supply of scarce organs, and concludes that presumed consent advocates "a policy that goes against the grain of American individualism and is more at home in countries with a stronger communitarian ethic."[182]

Parents deserve straightforward information about what will happen to their child's DNA sample, how their child's privacy will be protected, and, to the extent known, the type of research in which the sample will be used, and the conditions under which samples will be shared. Providing parents with clearly communicated written information about the state's newborn bloodspot storage and research program, and obtaining their voluntary written consent is beneficial in two important respects. First, obtaining written informed consent from parents exhibits a respect for parental autonomy in making decisions involving their child's body. It acknowledges the child whose information and blood are provided for research, and recognizes the parent's contribution to the advancement of medical science.[183] Second, engaging in the process of informed consent is an important part of gaining and maintaining the public trust in genetic research. Ultimately, science and society will benefit. As researchers in the hypothetical pediatric biobank study noted, "understanding correlated with enrollment."[184]

When parents are fully informed, and their choice is respected, they are more likely to trust the program, and want to participate. But merely to

180. *See id.* at 300(noting confusion about the privacy of the information and whether or not family members, law enforcement and researchers at other institutions could gain access to the information).

181. *Id.* at 299.

182. David Orentlicher, *Presumed Consent to Organ Donation: Its Rise and Fall in the United States*, 61 RUTGERS L. REV. 295, 296–297 (2009) (noting that presumed consent laws are more common in Austria, Belgium, France, Italy, and Sweden).

183. Ellen Wright Clayton, *supra* note 143, at 19.

184. Neidich et al., *supra* note 179, at 302.

presume that parents would consent to genetic research using their child's blood is . . . well, presumptuous . . . and inaccurate.[185] Equally misguided is the presumption that every parent who is opposed to storing their child's bloodspot for research will understand that they must take the initiative, and act affirmatively to exclude their child from future research. A presumed consent system for genetic research risks loss of public trust, and may ultimately undermine the essential newborn screening program. [186] The time is right for States to adopt the federal regulations for the protection of human subjects, and to require IRB review and approval of newborn bloodspot collection, storage, and dissemination procedures. A transparent approach, based on parental written informed consent, will go far in assuring the public's trust in essential state newborn screening programs.

185. *See id.* at 299 (indicating at least twenty percent of women would not consent to enrolling their child into a hypothetical biobank, thus hypothetically not consenting to the genetic research of their child's blood).

186. *See* Clayton, *supra* note 133, at 802 ("Ultimately, the silent creation of biobanks from clinical information and specimens turns out simply to be a bad idea, no matter what the law says.").