
Note

That's My Baby: Why the State's Interest in Promoting Public Health Does Not Justify Residual Newborn Blood Spot Research Without Parental Consent

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On November 4, 2008, Andrea Beleno gave birth to her son, Joaquin, in Austin, Texas.¹ Like 98% of babies born in the United States,² his heel was pricked and five drops of blood were collected and submitted to the Texas Department of State Health Services (TDSHS) as part of its mandatory newborn screening program.³ However, "in the haze after giving birth," Beleno neither knew about nor consented to the screening.⁴ Parental consent is not required for the initial screening,⁵ which

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1. Mary Ann Roser, *State Agrees to Destroy More than 5 Million Stored Blood Samples from Newborns*, AUSTIN AM.-STATESMAN, Dec. 22, 2009, <http://www.statesman.com/news/news/state-regional/state-agrees-to-destroy-more-than-5-million-stored/nRZK9/> [hereinafter Roser, *State Agrees to Destroy*].

2. VANI KILAKKATHI, COUNCIL FOR RESPONSIBLE GENETICS, NEWBORN SCREENING IN AMERICA: PROBLEMS AND POLICIES 4 (2012), available at <http://www.councilforresponsiblegenetics.org/pageDocuments/WNMAKEPP1P.pdf>.

3. *Government Taking Newborn DNA Samples*, KXAN (Nov. 24, 2009, 3:00 PM), <http://www.kxan.com/news/government-taking-newborn-dna-samples->; see also TEX. HEALTH & SAFETY CODE ANN. § 33.011(a) (2010) (requiring physician to draw newborn's blood to test for various genetic conditions specified by the Department of Health).

4. Roser, *State Agrees to Destroy*, *supra* note 1.

5. For a discussion of how newborn screening developed into a state-run program without an informed consent requirement, see Lainie Friedman Ross,

tests for a variety of conditions that can be effectively treated through early detection.⁶ Beleno sued TDSHS when she learned the state was storing newborn blood samples (NBS)⁷ “indefinitely” for research unrelated to the initial screening.⁸

Beleno did not object to the *initial* screening.⁹ What she found problematic was the potentially “indefinite” retention of her son’s genetic material and the unknown and undisclosed uses of the NBS.¹⁰ Two other recent lawsuits and a series of interviews demonstrate she is not alone in her concerns.¹¹ Beleno worried about the misuse of her son’s genetic information, such as in future employment or insurance discrimination.¹²

Beleno’s experience is not unusual given that all fifty states operate newborn screening programs.¹³ Proponents of the programs argue they are an important public health tool because they facilitate early detection of certain genetic diseases.¹⁴ For example, the major consequence of Phenylketonuria

Mandatory Versus Voluntary Consent for Newborn Screening?, 20 KENNEDY INST. ETHICS J. 299, 300–02 (2010).

6. See, e.g., KILAKKATHI, *supra* note 2, at 10 (relating the “numerous personal stories from parents whose children are able to lead normal, healthy lives because of early screening and treatment of various genetic conditions”).

7. Throughout this Note “NBS” will be used to refer to the synonymous terms “newborn blood samples” and “newborn blood spots.”

8. First Amended Complaint ¶ 12, *Beleno v. Tex. Dep’t of State Health Servs.*, No. SA-09-CA-0188-FB (W.D. Tex. dismissed Dec. 14, 2009), 2009 WL 5072239 [hereinafter *Beleno* Complaint].

9. *Id.* ¶ 15.

10. *Id.* ¶ 15–16.

11. See, e.g., *Bearder v. State*, 806 N.W.2d 766, 776 (Minn. 2011) (holding that the state statute regulating newborn blood tests does not authorize residual use and dissemination of NBS); Complaint ¶ 8, *Higgins v. Tex. Dep’t of State Health Servs.*, 801 F. Supp. 2d 541 (W.D. Tex. 2011) (No. 510-cv-00990) [hereinafter *Higgins* Complaint] (claiming the State “knowingly, deceptively . . . and without the knowledge or consent of the infants’ parents, sold . . . and distributed [NBS] . . . to . . . third parties”); Erin Rothwell et al., *Assessing Public Attitudes on the Retention and Use of Residual Newborn Screening Blood Samples: A Focus Group Study*, 74 SOC. SCI. & MED. 1305, 1307 (2012) (compiling parents’ opinions about residual NBS retention and use).

12. *Beleno* Complaint, *supra* note 8, ¶ 16.

13. See KILAKKATHI, *supra* note 2, at 29–37 for a chart with each state’s newborn screening program policies.

14. See, e.g., Rothwell et al., *supra* note 11, at 1305 (noting that “NBS is a core service for public health” and that testing “identif[ies] infants at high risk for particular conditions and would benefit from early treatment”); Michael S. Watson et al., *Newborn Screening: Toward a Uniform Screening Panel and System*, 8 GENETICS IN MED., May 2006, at 12S, 15S, available at https://www.acmg.net/resources/policies/NBS/NBS_Main_Report_00.pdf (“[N]ewborn

(severe mental retardation) can be prevented through early detection and implementation of a low phenylalanine diet.¹⁵ But Beleno, and others, primarily take issue with the unclear and undisclosed state policies regulating storage and use of NBS that remain *after* the initial screenings and follow-up tests are completed.¹⁶ Parents and patient advocacy groups raise additional concerns, including: (1) the lack of informed consent required for residual NBS use in research; (2) privacy concerns; and (3) whether states have legitimate justifications to store and use residual NBS without parental consent.¹⁷

The focus of this Note is on the state's role in residual NBS storage and use and whether its interest in promoting public health is compelling enough to overcome well-recognized parental rights to consent to their children's medical treatment and research participation.¹⁸ The analysis draws on precedent discussing the scope of the state's right to infringe on individual liberties in the interest of public health. In this context, this Note evaluates whether those cases in which the state's interest has prevailed are sufficiently analogous to apply to the state's use of residual NBS without parental consent.

This Note argues that the government's interest in and obligation to promote public health do *not* justify non-consensual use of NBS. Part I provides an overview of police power jurisprudence, existing state policies regulating residual NBS storage and use, and previous litigation disputing state policies and practices. Part II discusses the possible public health justifications for using residual NBS without parental consent and

screening is a highly visible and important State-based public health program").

15. KILAKKATHI, *supra* note 2, at 5.

16. See *Beleno Complaint*, *supra* note 8, ¶¶ 12–18; see also KILAKKATHI, *supra* note 2, at 4 (“[T]here is also little transparency regarding storage procedures or the use of the samples *after* they have been screened.”) (emphasis added); Rothwell et al., *supra* note 11, at 1305 (noting that research projects conducted after the initial screening and without parental consent “raise[] several ethical and legal dilemmas”).

17. For a discussion of the issues raised by screening, storage, and use of residual NBS, see KILAKKATHI, *supra* note 2, at 12–23.

18. See, e.g., COMM. ON CLINICAL RES. INVOLVING CHILDREN, THE ETHICAL CONDUCT OF CLINICAL RESEARCH INVOLVING CHILDREN 146 (Marilyn J. Field & Richard E. Behrman eds., 2004) (discussing parents' legal authority to consent to their child's participation in research); Comm. on Bioethics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 PEDIATRICS 314, 317 (1995) (“[I]n most cases, physicians have an ethical (and legal) obligation to obtain parental permission to undertake[] recommended medical interventions.”).

whether this is an appropriate and permissible mechanism to fulfill the government's obligation to promote public health. Part III concludes that the state's interest in promoting public health, although important, does not justify a blanket waiver of parental consent. Part III then proposes a policy that states can, and should, implement to increase transparency and ensure that parental rights and children's rights are respected while still promoting public health through medical research that aims to detect new conditions, develop new treatments, and eradicate disease.

I. GOVERNMENTAL INTEREST IN PUBLIC HEALTH AND NBS LAWS AND RECENT LITIGATION

Part I proceeds in three parts. Part A addresses the tensions emerging from jurisprudence discussing state police powers, providing a descriptive account of the limitations on state police power. Part B briefly describes current state laws governing residual NBS retention and use. Part C then discusses recent litigation disputing residual NBS use in Minnesota and Texas.

A. PRECEDENT RECOGNIZING THE STATE'S INTEREST IN PROTECTING AND PROMOTING PUBLIC HEALTH

According to the Institute of Medicine, public health is "what we, as a society, do *collectively* to assure the conditions for people to be healthy," a definition which "reinforces that collective entities (governments and communities) are responsible for healthy populations."¹⁹ Because public health research and regulations aim to benefit the community as a whole, tensions ultimately arise between collective benefits and individual rights and interests.²⁰

Notwithstanding these tensions, government intervention to promote public health has long been valued and viewed as an "unmitigated good."²¹ The government frequently capitalizes on

19. Lawrence O. Gostin, *Public Health*, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 143 (Mary Crowley ed., 2008) (emphasis added) (internal quotation marks omitted), *available at* http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/public%20health%20chapter.pdf.

20. *Id.* (noting that public health regulations and interventions often "encroach on fundamental civil liberties such as privacy [and] bodily integrity").

21. Lawrence O. Gostin, *General Justifications for Public Health Regulation*, 121 PUB. HEALTH 829, 829 (2007).

this conventional belief to justify public health interventions that restrict individual liberties.²² Furthermore, courts have repeatedly affirmed the state's legitimate interest in protecting public health and safety.²³ This authority to protect public health and welfare falls within a state's "police power," a power which "extends . . . to the protection of the lives, limbs, health, comfort, and quiet of all persons."²⁴

Although Supreme Court rulings hold there is "no question" that states have the "perfect right" to exercise their police powers when necessary,²⁵ statutes and case law illustrate that such rights *are* tempered.²⁶ Throughout history and across a broad set of law and public health controversies, such as quarantine, mandatory vaccinations, prescription drug reporting requirements, and public smoking bans, courts have affirmed states' use of police powers to protect public health while simultaneously acknowledging the powers' limits.²⁷

22. Examples include infectious disease controls such as quarantines and mandatory vaccinations, public smoking restrictions, and restricting access to unhealthy foods to reduce obesity. *See id.* at 830–32.

23. *See Slaughter-House Cases*, 83 U.S. (16 Wall.) 36, 62 (1872) ("[P]ersons and property are subject to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the State."); *see also NYC C.L.A.S.H., Inc. v. City of New York*, 315 F. Supp. 2d 461, 492 (S.D.N.Y. 2004) (noting the "well-recognized and far-reaching police power of the state over the health and welfare of its citizens").

24. *Slaughter-House Cases*, 83 U.S. at 62 (internal quotation marks omitted).

25. *Id.*

26. For example, many state quarantine laws require a state to have "clear and convincing evidence" that the infringements will achieve its goals and do so by using the "least restrictive means" possible to achieve these goals. DEL. CODE ANN. tit. 20, § 3136 (2005); *see also* HAW. REV. STAT. ANN. § 325–8(g) (West 2008); IND. CODE ANN. § 16-41-9-1.5 (LexisNexis 2011); MINN. STAT. ANN. § 144.419 (West 2011).

27. The following cases, while not an exhaustive list, illustrate this jurisprudence.

1. Quarantine: *Compagnie Francaise de Navigation a Vapeur v. Louisiana State Board of Health*²⁸

In 1898, the plaintiff, a French corporation, sent a ship to New Orleans with cargo and over 400 passengers.²⁹ Although there was no evidence of infected passengers, the ship was not allowed to unload her cargo or passengers upon arrival in New Orleans.³⁰ This was due to a recently adopted regulation giving the state board of health the authority to “prohibit the introduction into any infected portion of the State, persons acclimated, unacclimated, or said to be immune, when in its judgment the introduction of such persons would add to or increase the prevalence of the disease.”³¹ The regulation’s goal was to reduce the number of infected individuals and prevent the spread of disease.³² When the ship landed, New Orleans was under quarantine and thus the passengers were not allowed to disembark the ship.³³

In his opinion for the Court, Justice White referred to a state’s historically recognized power to enact and enforce quarantine laws to protect its citizens’ health and safety.³⁴ He concluded that laws intending to prevent, eradicate, or control the spread of communicable diseases do not violate the Constitution.³⁵ Importantly, however, Justice White noted that if a state uses its police power in a way that is “repugnant” to the Constitution, the Constitution “must prevail.”³⁶

2. Compulsory Vaccination: *Jacobson v. Massachusetts*³⁷

In 1902, Cambridge, Massachusetts’s board of health adopted a regulation requiring all city inhabitants to be vaccinated or revaccinated for smallpox because of the disease’s in-

28. 186 U.S. 380 (1902). Most states also have public health laws specific to quarantine procedures. *See, e.g.*, DEL. CODE ANN. tit. 20, § 3136; IND. CODE ANN. § 16-41-9-1.5; MINN. STAT. ANN. § 144.419; *see also State Quarantine and Isolation Statutes*, NAT’L CONF. STATE LEG., <http://www.ncsl.org/issues-research/health/state-quarantine-and-isolation-statutes.aspx> (last updated Aug. 2010) (listing state quarantine and isolation laws).

29. *Compagnie Francaise*, 186 U.S. at 381–82.

30. *Id.* at 382.

31. *Id.* at 385.

32. *Id.*

33. *Id.* at 382.

34. *Id.* at 387.

35. *Id.*

36. *Id.* at 387–88.

37. 197 U.S. 11 (1905).

creased prevalence in the city.³⁸ The regulation was enacted under a state law giving the board of health the authority to require and enforce vaccination or revaccination when “necessary for the public health or safety.”³⁹

The State filed criminal charges against Jacobson after he refused to comply with the vaccination requirement.⁴⁰ Jacobson alleged that the Massachusetts law violated his Fourteenth Amendment rights.⁴¹ He was found guilty and the case eventually reached the Supreme Court. The main issue the Court addressed was whether a statute requiring a person to submit to vaccination was unconstitutional.⁴² The Court upheld the mandate, concluding that based on the “principle of self-defense . . . a community has the right to protect itself against an epidemic of disease which threatens the safety of its members” and that the statute was a “reasonable and proper exercise of the [state’s] police power.”⁴³

Similar to Justice White in *Compagnie Francaise*,⁴⁴ Justice Harlan, delivering the opinion of the Court, made clear that police powers are limited and acknowledged that individuals have the right to dispute governmental interference with the exercise of their freedom.⁴⁵ If police powers are used inappropriately, arbitrarily, or oppressively, the courts may justifiably intervene “to prevent wrong and oppression.”⁴⁶

3. Reporting Schedule II Drug Prescriptions: *Whalen v. Roe*⁴⁷

Police powers are also invoked in contexts beyond infectious disease prevention. In 1972, the New York State Legislature enacted a law requiring physicians to provide the state with information about all Schedule II drug prescriptions.⁴⁸ Its purpose was to prevent potentially dangerous drugs from enter-

38. *Id.* at 12.

39. *Id.*

40. *Id.* at 13.

41. *Id.* at 14.

42. *Id.* at 24.

43. *Id.* at 27, 35.

44. *Compagnie Francaise de Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380, 388 (1902).

45. *Jacobson*, 197 U.S. at 38.

46. *Id.*

47. 429 U.S. 589 (1977).

48. *Id.* at 591–93. Schedule II drugs are those considered “the most dangerous of the legitimate drugs,” such as opium, methadone, amphetamines, and methaqualone. *Id.* at 593 & n.8.

ing illegal markets.⁴⁹ The required information included the prescribing physician's name, the dispensing pharmacy, the drug and dosage, and the patient's name, address, and age.⁵⁰ The information was then stored in a secure computer system managed by the State Department of Health.⁵¹ Under the statute, it was a crime to publicly disclose information in these records.⁵² Physicians and patients claimed the law violated their right to privacy, intruded upon the doctor-patient relationship, and was "needlessly broad."⁵³

The Court upheld the statute, concluding it was a reasonable exercise of the state's police power.⁵⁴ In his concurrence, Justice Brennan, like his predecessors, noted the power's limits and reserved the Court's right to intervene in the future: "The central storage and easy accessibility of computerized data vastly increase the potential for abuse of that information, and I am not prepared to say that future developments will not demonstrate the necessity of some curb on such technology."⁵⁵

4. Public Smoking Bans

Two final examples involve public smoking bans. In 2003, New York amended the Clean Indoor Air Act to prohibit indoor smoking where people socialize or work.⁵⁶ The law was passed in response to increasing scientific and medical evidence establishing a correlation between "environmental tobacco smoke" (ETS) (second-hand smoke) and severe health risks to non-smokers.⁵⁷ NYC C.L.A.S.H., a smokers' rights lobbying group,⁵⁸ filed a lawsuit claiming various constitutional violations, with particular focus on the First Amendment.⁵⁹

49. *Id.* at 591.

50. *Id.* at 593.

51. *Id.* at 593-94.

52. *Id.* at 594-95.

53. *Id.* at 596.

54. *Id.* at 597-98.

55. *Id.* at 607.

56. NYC C.L.A.S.H., Inc. v. City of New York, 315 F. Supp. 2d 461, 466 (S.D.N.Y. 2004).

57. *Id.*

58. NYC C.L.A.S.H. stands for "Citizens Lobbying Against Smoker Harassment." Its goal is to "end the discrimination against smokers by exposing the anti-smoking lies." NYC C.L.A.S.H., <http://www.nycclash.com> (last visited Oct. 17, 2013).

59. NYC C.L.A.S.H., 315 F.Supp. 2d at 467-68.

In its analysis, the court emphasized the significant and widely recognized evidence of ETS's harms.⁶⁰ The court applied a rational basis test under which there need only be "some 'reasonably conceivable state of facts that could provide a rational basis'" to uphold a statute.⁶¹ Relying heavily on the evidence of ETS's harms, the court concluded that the smoking ban's intended goal—to protect the public "from the well-documented harmful effects of ETS"—provided a sufficient rational basis to uphold the ban.⁶²

Ohio voters passed a similar law in 2006, the "Smoke Free Workplace Act," which prohibits smoking in "public places of employment."⁶³ A bar owned by Bartec Inc. failed to comply with the Act and was cited for numerous violations, prompting the Ohio Department of Health to file a complaint seeking injunctive relief to order compliance with the Act.⁶⁴ Bartec counterclaimed, alleging in part that the Act "exceed[ed] the limits of the state's police powers."⁶⁵

The Ohio Supreme Court disagreed with Bartec, recognizing that property rights granted by the Ohio Constitution were not absolute and could be subjected "to a reasonable, nonarbitrary exercise of the police power . . . when exercised in the interest of public health, safety, morals, or welfare."⁶⁶ According to the court, a law is in the interest of public health and welfare if it is "reasonable, not arbitrary, and . . . confer[s] upon the public a benefit commensurate with its burdens . . ."⁶⁷ The court upheld the Act, concluding it was a proper use of the state's police power and was "neither unduly oppressive nor arbitrary in its restrictions."⁶⁸

Although far from exhaustive, these cases illustrate that across a broad set of law and public health controversies, courts recognize and affirm use of police powers to protect public health but also acknowledge the power must be limited to protect individual freedom. Because of the potential public health

60. *Id.* at 497.

61. *Id.* at 486 (quoting *Heller v. Doe*, 509 U.S. 312, 320 (1993)).

62. *Id.* at 492.

63. *Wymyslo v. Bartec, Inc.*, 970 N.E.2d 898, 902 (Ohio 2012).

64. *Id.*

65. *Id.* at 912. Bartec also filed a cross-claim against the Ohio Attorney General. *Id.* at 902.

66. *Id.*

67. *Id.* at 913 (quoting *Direct Plumbing Supply Co. v. Dayton*, 38 N.E.2d 70, 73 (1941)).

68. *Id.* at 914.

benefits of residual NBS research and the corresponding risks to and infringement upon personal privacy, residual NBS use without informed parental consent raises the question of whether the state's police power can be invoked in this context.

B. RESIDUAL NBS RETENTION AND USE: STATE LAWS

Newborn blood screenings are performed in all fifty states⁶⁹ and test for a variety of conditions that are life-threatening if not diagnosed and treated shortly after birth.⁷⁰ However, the state policies and regulations governing the specific tests performed and the retention and use of residual NBS are not uniform,⁷¹ and parental consent is often not required for the initial screenings.⁷² And although a majority of parents are aware of the *initial* screening,⁷³ knowledge about residual retention and use is more limited.⁷⁴ Many parents are unaware that their child's blood may be kept and stored for a number of years, if not indefinitely, during which time the NBS may be used in research unrelated to the initial screening.⁷⁵

A survey of legislation governing consent procedures for residual NBS storage and use indicates a wide and inconsistent range of policies.⁷⁶ Oklahoma, for example, stores the bloodspots for forty-two days and requires written parental consent for continued storage and research use.⁷⁷ On the other end of the spectrum, North Dakota stores the samples indefinitely with no specific consent required, allows the samples to be used for "medical, psychological, or sociological research," and per-

69. Michelle H. Lewis et al., *State Laws Regarding the Retention and Use of Residual Newborn Screening Blood Samples*, 127 PEDIATRICS 703, 704 (2011). For an example of a state statute governing the initial screening requirement, see MINN. STAT. ANN. § 144.125 (West 2011).

70. See Lewis et al., *supra* note 69, at 707.

71. See News Release, Johns Hopkins Univ. Genetics & Pub. Pol'y Ctr., Most States Unclear About Storage, Use of Baby Blood Samples, New Study Finds (Mar. 30, 2011) [hereinafter News Release, Johns Hopkins], available at http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=143 ("State laws and policies governing the storage and use of [residual NBS] . . . range from explicit to non-existent . . .").

72. See Lewis et al., *supra* note 69, at 704.

73. In one study, 55% of parents knew the screening had been performed. Jeffrey R. Botkin et al., *Public Attitudes Regarding the Use of Residual Newborn Screening Specimens for Research*, 129 PEDIATRICS 231, 233 (2012).

74. See *id.* at 233–37.

75. KILAKKATHI, *supra* note 2, at 15.

76. See *id.* at 29–37.

77. *Id.* at 35.

mits the state to “charge for access to specimens.”⁷⁸ Even when parents are told that research may be conducted using NBS, the reasons given for the research are often broad (e.g., “research with a significant health benefit”⁷⁹) and provide little, if any, specific information to parents. Newborn screening information is “confidential” in only twenty-six states, but “confidentiality” does not necessarily require removal of identifying DNA information from the blood spots.⁸⁰ The idea of confidentiality is thus misleading because it is possible to trace NBS back to the specific infants they were obtained from.⁸¹

Unclear and inexplicit state laws governing residual NBS storage and use have resulted in a lack of comprehensive and transparent policies, leaving parents and health-care providers ill-informed.⁸² As a result, residual NBS have been the center of recent public debate and litigation.

C. RECENT NBS LITIGATION

Newborn screening practices bring to the fore legal and ethical tensions between the state and its citizenry. Researchers, physicians, and public health officials contend that residual NBS research promotes public health because it may lead to advancements in disease diagnosis and treatment that will benefit both the individual children from whom the samples were obtained and society as a whole.⁸³ The destruction of millions of NBS required by recent disputes⁸⁴ is troubling to public health officials and researchers who consider it a

78. *Id.*

79. Lewis, *supra* note 69, at 705.

80. *Id.* at 705–06.

81. *Id.*

82. News Release, Johns Hopkins, *supra* note 71.

83. Peggy Fikac, *State to Destroy Newborns' Blood Samples*, HOUS. CHRON., Dec. 22, 2009, <http://www.chron.com/news/houston-texas/article/State-to-destroy-newborns-blood-samples-1599212.php>; see also Bradford L. Therrell et al., *Committee Report: Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens After Newborn Screening*, 13 GENETICS MED. 621, 623 (2011) (discussing studies showing that use of residual NBS to develop tests has “accelerated” discoveries and has had “direct public health benefits”).

84. See, e.g., *Bearder v. State*, 806 N.W.2d 766, 776 (Minn. 2011) (concluding that the Minnesota Department of Health could not store NBS beyond its statutory authorization and remanding for determination of remedy); *Higgins v. Tex. Dep't of State Health Servs.* 801 F. Supp. 2d 541, 545–46 (W.D. Tex. 2011) (discussing the *Beleno* settlement, which required destruction of NBS); *Beleno v. Tex. Dep't of State Health Servs.*, No. SA-09-CA-0188-FB (W.D. Tex. dismissed Dec. 14, 2009).

loss of great magnitude: “a superb database has been lost. This database could have continued to shed light on causes of congenital birth defects and potentially led to preventative measures saving thousands of infants and their families the distress these defects cause.”⁸⁵ There is also concern that more detailed and time-consuming informed consent procedures will increase costs, making research prohibitively expensive.⁸⁶

On the other side are parents concerned about parental rights, privacy, and protection of their child’s sensitive genetic information.⁸⁷ The lack of information provided to parents about residual NBS use was a catalyst for recent litigation in Texas and Minnesota.

1. Texas Lawsuits

In *Beleno v. Texas Department of State Health Services*, Andrea Beleno, on behalf of the class of parents and their infant children, alleged that the Texas Department of State Health Services (TDSHS) and Texas A&M University (TAMU) Health Science Center “unlawfully and deceptively collected blood samples from their children at [the] time of birth and stored those samples indefinitely for undisclosed research purposes, without Plaintiff’s knowledge or consent”⁸⁸ Beleno filed the lawsuit after learning her son’s NBS were being stored at TAMU for research.⁸⁹ According to the complaint, the Defendants’ policies and practices violated both the law and the standard protocol of obtaining informed consent prior to any study involving human subjects.⁹⁰ The parties settled and the

85. Fikac, *supra* note 83 (quoting the President of Texas A&M Health Science Center).

86. For example, geneticist David Segal estimates that such changes could increase administrative costs for the University of California by up to \$594,000 annually. Helen Shen, *California Considers DNA Privacy Law*, NATURE, May 18, 2012, <http://www.nature.com/news/california-considers-dna-privacy-law-1.10677>.

87. See *Bearder*, 806 N.W.2d at 769; *Higgins*, 801 F. Supp. 2d at 544; *Beleno*, No. SA-09-CA-0188-FB.

88. *Beleno* Complaint, *supra* note 8, at 1.

89. See *id.* ¶ 12; *Texas to Destroy Unauthorized Blood Samples*, ASSOCIATED PRESS (Dec. 23, 2009), http://www.boston.com/news/nation/articles/2009/12/23/texas_to_destroy_unauthorized_blood_samples/?camp=pm.

90. *Beleno* Complaint, *supra* note 8, ¶ 18. This section of the complaint refers to the human research subjects protections promulgated in 45 C.F.R. Part 46, of which subpart A is frequently referred to as the “Common Rule.” *Federal Policy for the Protection of Human Subjects (“Common Rule”)*, U.S. DEPT HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/commonrule/> (last visited Oct. 17, 2013) [hereinafter *Common Rule*].

case was dismissed with prejudice; thus no court judgment was rendered.⁹¹ As part of the settlement, TDSHS agreed to destroy approximately 4.5–5 million samples taken and stored without parental consent between 2002 (when TDSHS began retaining NBS for research) and May 27, 2009.⁹²

Despite the settlement, the battle continued. In 2010, Jim Harrington, lawyer for the *Beleno* plaintiffs, learned that between 2003 and 2007 approximately 800 NBS were sent to the United States military to create a “national mitochondrial DNA database.”⁹³ The database was never mentioned during the lawsuit, and Harrington claimed he was repeatedly assured that the NBS were used only for medical research and not law enforcement purposes.⁹⁴ A new class action lawsuit was filed, claiming that TDSHS “deceptively [and] unlawfully . . . sold, traded, bartered, and distributed [NBS] . . . to private research companies, government agencies, and other third parties,” including the Armed Forces Institute of Pathology.⁹⁵ Although the case was ultimately dismissed for lack of standing,⁹⁶ it illustrates continuing questions and concerns about residual NBS research.

2. Minnesota: *Bearder v. State*⁹⁷

In contrast to the settled⁹⁸ or dismissed⁹⁹ disputes in Texas, the Minnesota Supreme Court issued a full opinion on a similar

91. See Order of Dismissal, with Prejudice, *Beleno v. Lakey*, No. SA-09-CA-188-FB (W.D. Tex. Dec. 14, 2009); Becca Aaronson, *Lawsuit Alleges DSHS Sold Baby DNA Samples*, TEX. TRIB., Dec. 8, 2010, <http://www.texastribune.org/2010/12/08/lawsuit-alleges-dshs-sold-baby-dna-samples/>.

92. Katherine Drabiak-Syed, *Newborn Blood Spot Banking: Approaches to Consent*, PREDICTER L. & POL'Y UPDATE, (Ind. Univ. Ctr. Bioethics, Indianapolis, Ind.), Mar. 12, 2010, at 10, available at http://bioethics.iu.edu/index.php/download_file/view/91/.

93. Mary Ann Roser, *Suit Possible over Baby DNA Sent to Military Lab for National Database*, AUSTIN AM.-STATESMAN, Feb. 22, 2010, <http://www.statesman.com/news/news/state-regional-govt-politics/suit-possible-over-baby-dna-sent-to-military-lab-1/nRqkT/>.

94. *Id.*

95. *Higgins* Complaint, *supra* note 11, ¶ 8; see also Aaronson, *supra* note 91 (discussing the state's trade of NBS for lab supplies and services valued around half a million dollars from a private company).

96. *Higgins v. Texas Dep't of Health Servs.*, 801 F. Supp. 2d 541, 553, 555 (W.D. Tex. 2011).

97. 806 N.W.2d 766 (Minn. 2011).

98. See Order of Dismissal, with Prejudice, *Beleno v. Lakey*, No. SA-09-CA-188-FB (W.D. Tex. Dec. 14, 2009). Prior to dismissal, the parties settled. See *id.*

issue in *Bearder v. State* in 2011.¹⁰⁰ What was unique about *Bearder* was that the Plaintiffs brought a cause of action under Minnesota's Genetic Privacy Act (GPA),¹⁰¹ which "protects the genetic privacy and DNA property rights of all Minnesotans, including newborns."¹⁰² The statute provides that an individual's genetic information may only be collected with the individual's written informed consent, used for the purposes specified by the informed consent, used only for the length of time consented to, and cannot be disseminated to other parties without additional written informed consent.¹⁰³ According to the Plaintiffs, the state stored the NBS without parental consent and shared the samples with private entities and hospitals.¹⁰⁴

Minnesota's policy was to retain residual NBS unless there was a specific request that the samples be destroyed.¹⁰⁵ As of December 31, 2008, more than 800,000 NBS were stored, dating back to 1997, and more than 50,000 NBS had been used in studies for purposes unrelated to the initial newborn screenings.¹⁰⁶ The majority of NBS research uses "de-identified" samples,¹⁰⁷ and under the current federal regulation known as the "Common Rule,"¹⁰⁸ studies involving de-identified health records and information are exempt from federal privacy protec-

99. See *Higgins*, 801 F. Supp. 2d at 553, 555. The case was dismissed for lack of standing. *Id.*

100. *Bearder*, 806 N.W.2d.

101. MINN. STAT. ANN. § 13.386 (West 2011) (granting a statutory right to privacy of genetic information).

102. First Amended Complaint at 34, *Bearder v. State*, 806 N.W.2d 766 (Minn. 2011) (No. 09-5615), 2009 WL 5427622 [hereinafter *Bearder* Complaint].

103. MINN. STAT. ANN. § 13.386.

104. *Bearder* Complaint, *supra* note 102, at 4.

105. *Bearder*, 806 N.W.2d at 770.

106. *Id.* at 770-71.

107. *Id.* at 771. A de-identified sample is coded and separated from identifiers, but identifiers are kept and can be retrieved so that the sample can be linked back to the individual. In contrast, anonymous samples lack identifiers to link back to the donor. For an explanation of anonymous and de-identified samples, see STEVE OLSON & ADAM C. BERGER, CHALLENGES AND OPPORTUNITIES IN USING RESIDUAL NEWBORN BLOOD SCREENING SAMPLES FOR TRANSLATIONAL RESEARCH: WORKSHOP SUMMARY 31-32 (2010), available at http://www.nap.edu/openbook.php?record_id=12981&page=31; Mark A. Rothstein, *Is Deidentification Sufficient to Protect Health Privacy in Research?*, AM. J. BIOETHICS, Sept. 2010, at 3.

108. See *Common Rule*, *supra* note 90.

tions and federal regulations governing human subject research.¹⁰⁹

The Plaintiffs filed a number of claims, including violation of the GPA.¹¹⁰ The State argued it did not violate the GPA because (1) blood samples are not “genetic information” under the GPA; and (2) Minnesota’s “newborn screening statutes ‘expressly provide’ that the Department of Health may use, store, and disseminate . . . genetic information without first obtaining written informed consent.”¹¹¹ The district court granted the State’s motion to dismiss¹¹² and the court of appeals affirmed.¹¹³ The Minnesota Supreme Court reversed, concluding that “genetic information” under the GPA “includes the actual blood samples as ‘medical or biological’ information.”¹¹⁴ Therefore NBS *are* protected by the GPA, which requires “written informed consent to collect, use, store, or disseminate those samples.”¹¹⁵ In response to the State’s claim that the newborn screening statutes exempted it from the informed consent requirement, the court held that the statutes provide an exemption from the GPA requirements only for “testing the samples for . . . disorders, recording and reporting those test results, maintaining a registry of positive [results], and storing those

109. For instance, 45 C.F.R. § 46.101(b)(4) (2012) states that “[r]esearch, involving the collection or study of . . . specimens” is exempt from § 46 protections such as Institutional Review Board (IRB) approval and informed consent “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.” The regulations comprising § 46 embody many of the ethical principles and guidelines articulated in “The Belmont Report.” See Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Fed. Reg. 23,192 (Apr. 18, 1979) [hereinafter The Belmont Report]. Similarly, 45 C.F.R. § 164.514 excludes health information “that does not identify an individual and . . . there is no reasonable basis to believe that the information can be used to identify an individual.” There are also exceptions to § 164.514, the Health Insurance Portability and Accountability Act (HIPAA) “Privacy Rule.” Rothstein, *supra* note 107, at 4.

110. *Bearder* Complaint, *supra* note 102, at 5.

111. *Bearder v. State*, 806 N.W.2d 766, 771–72 (Minn. 2011).

112. *Bearder v. State*, No. 27-CV-09-5615, 2009 WL 5454446 (Minn. Dist. Ct., Nov. 24, 2009), *aff’d*, 788 N.W.2d 144 (Minn. Ct. App. 2010), *rev’d*, 806 N.W.2d 766 (Minn. 2011).

113. *Bearder v. State*, 788 N.W.2d 144 (Minn. Ct. App. 2010), *rev’d* 806 N.W.2d 766 (Minn. 2011).

114. *Bearder*, 806 N.W.2d at 774.

115. *Id.*

results as required by federal law.”¹¹⁶ The exemptions do not authorize the state to use, store, or disseminate the samples for other purposes.¹¹⁷

As a result of the court’s decision, the Minnesota Department of Health was ordered to destroy all NBS after they are stored for seventy-one days.¹¹⁸ The destruction includes all NBS collected on or after the Minnesota Supreme Court decision on November 16, 2011.¹¹⁹

Bearder represents the first, but likely not the last, court decision limiting state use of residual NBS without informed parental consent. Because of the potential public health benefits of residual NBS research, state policies should be scrutinized to determine whether the policies are justified under a state’s police powers or whether changes must be made to include an informed consent procedure.

II. PUBLIC HEALTH AND RESIDUAL NBS RESEARCH

Supreme Court jurisprudence discussing a state’s interest in public health indicates that states may act to prevent or reduce the risk of *harm* to the public even if such protection requires infringing on individual rights, autonomy, and privacy.¹²⁰ The infringements involved in using NBS without parental consent, however, cannot be justified by the reasoning used in the previously discussed case law.¹²¹ Part A of this section discusses important differences between governmental use of residual NBS for public health research and the state poli-

116. *Id.* at 776.

117. *Id.* at 1.

118. News Release, Minn. Dep’t of Health, Minnesota Department of Health to Begin Destroying Newborn Blood Spots in Order to Comply with Recent Minnesota Supreme Court Ruling (Jan. 31, 2012) [hereinafter News Release, Minn. Dep’t of Health], *available at* <http://www.health.state.mn.us/news/pressrel/2012/newborn013112.html>.

119. *Id.*

120. *See, e.g.,* *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905) (“There are manifold restraints to which every person is necessarily subject for the common good. . . . Real liberty for all could not exist under the operation of the principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.”). Justice Harlan noted that the Court had “more than once recognized it as a fundamental principle that ‘persons and property are subjected to all kinds of restraints and burdens, in order to secure the general comfort, health, and prosperity of the state.’” *Id.* (quoting *Hannibal & St. J.R. Co. v. Husen*, 95 U.S. 465, 471 (1877)).

121. *See supra* Part I.A for a discussion of precedent.

cies at issue in precedent, arguing that there is a frequently ignored distinction between protection and promotion of public health and that in both circumstances the risks and benefits must be weighed. Part B then scrutinizes *who* actually benefits from the research, given the tenuous connections between residual NBS research and public health benefits discussed in Part A.

A. PROTECTING VERSUS PROMOTING THE PUBLIC HEALTH:
WEIGHING THE RISKS AND BENEFITS

The precedent cases address state laws and policies that infringe on individual rights primarily to *protect* the public from other individuals' actions or behaviors such as smoking,¹²² illegal drug sales,¹²³ or spreading communicable diseases.¹²⁴ In such circumstances, statutes and case law recognize a state's right to police individual behavior to prevent *harms* to innocent society members.¹²⁵ As a society, we value individual freedom but recognize its limits when such freedom endangers the welfare of others.¹²⁶ Residual NBS research, however, is more about public health *promotion*¹²⁷ rather than *protection*—and there is an important difference between the two. In either context, it is important to weigh the benefits of any policy requiring restrictions on individual rights.

1. Residual NBS Research: Protection or Promotion?

Quarantine laws, vaccination laws, and public smoking bans provide clear, well-documented public protections.¹²⁸ The

122. NYC C.L.A.S.H., Inc. v. City of New York, 315 F. Supp. 2d 461, 466 (S.D.N.Y. 2004); Wymyslo v. Bartec, Inc., 970 N.E.2d 898, 904–05 (Ohio 2012).

123. Whalen v. Roe, 429 U.S. 589, 591–93 (1977).

124. *Jacobson*, 197 U.S. at 34–35 (construing *Viemeister v. White*, 72 N.E. 97 (N.Y. 1904)); *Compagnie Francaise de Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380, 381 (1902).

125. See *supra* Part I.A.

126. According to John Stuart Mill, “The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.” JOHN STUART MILL, ON LIBERTY 22 (1859).

127. Public health promotion may occur, for example, by facilitating discovery of new diseases or treatments.

128. See, e.g., U.S. Dep't of Health & Human Servs., *Community Immunity* (“*Herd Immunity*”), VACCINES.GOV., <http://www.vaccines.gov/basics/protection/index.html> (last updated Oct. 16, 2013) [hereinafter *Community Immunity*] (noting that when the majority of people are immunized, the rest of the community is usually protected because there is little opportunity for an outbreak).

harms to be avoided can be clearly articulated—such as preventing the spread of contagious diseases¹²⁹—and the methods used by the states are usually taken only after consideration of *less-intrusive* measures. Delaware’s isolation/quarantine law, for example, is only used “during a state of emergency” and requires the State to use the “*least restrictive means necessary*” to prevent disease transmission.¹³⁰ Similarly, during a public health emergency, Virginia law authorizes the State Health Commissioner to “requir[e] immediate immunization of all persons.”¹³¹ Public smoking bans have been upheld and their justifications buttressed by significant evidence of ETS’s harms,¹³² and are further supported by evidence that such bans have successfully reduced tobacco-related illnesses.¹³³ Underlying these court decisions is a recognition that the harms to be avoided outweigh the possible harms caused by infringements on individual rights.¹³⁴

In contrast, there is no similar clarity about health protections from residual use of NBS.¹³⁵ Public health officials and researchers imply that harms *could* result if NBS are unavailable for research. Officials in Minnesota, for example, argue that destroying the residual NBS data bank “will compromise [the state’s] ability to assure the quality and accuracy of the newborn screening program,” suggesting that harms may occur

129. *Jacobson*, 197 U.S. at 34; *Compagnie Francaise*, 186 U.S. at 381.

130. DEL. CODE ANN. tit. 20, § 3136(1)(c) (2005) (emphasis added). Many other states have similar “least restrictive means necessary” requirements in their quarantine statutes. *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-788 (2009); MINN. STAT. ANN. § 144.419 (West 2011); N.J. STAT. ANN. § 26:13-15 (West 2007).

131. The only exception is if a physician certifies, in writing, that the vaccine could be harmful to the particular individual. VA. CODE ANN. § 32.1-48 (2011).

132. “[T]he evidence against ETS is consistent, profound, and widely-accepted.” NYC C.L.A.S.H., Inc. v. City of New York, 315 F. Supp. 2d 461, 497 (S.D.N.Y. 2004).

133. In addition to reducing tobacco-related illnesses, there is evidence that smoking bans may also reduce alcohol abuse. *See Smoking Bans in Bars Help Drinkers Drink Less Too, Yale Study Shows*, YALE NEWS (Sept. 24, 2012), <http://news.yale.edu/2012/09/24/smoking-bans-bars-help-drinkers-drink-less-too-yale-study-shows> [hereinafter *Smoking Bans in Bars*].

134. In *Jacobson*, the Court agreed with “most of the members of the medical profession” that the risk of harm from a vaccination is “generally . . . *too small to be seriously weighed as against the benefits* coming from . . . use of the preventive” 197 U.S. at 24 (emphasis added).

135. *See KILAKKATHI, supra* note 2, at 11 (discussing the “mismatch” between promised and actual benefits of research using NBS).

from inaccurate test results.¹³⁶

Yet even if the “harms” do occur, they are neither as clear nor as compelling as those at issue in the case law. And perhaps more importantly, there are less intrusive methods available to ensure an adequate supply of residual NBS for research, such as an opt-in informed consent procedure, which will be discussed below.¹³⁷

In addition to the protection-based argument, states are also interested in *promoting* societal health and well-being by using NBS to conduct research that aims to discover new diseases and develop new and improved therapies.¹³⁸ Arguments based on public health *promotion* rather than protection are even more problematic and lack a firm grounding in either statutory or case law previously discussed.¹³⁹ Researchers and the public health community tend to default to a public health promotion rationale despite the speculative nature of these claims. However, the inherent uncertainty in medical research limits the ability to promise or guarantee society-wide benefits.¹⁴⁰ In an era of impressive medical and scientific advancements and grand promises for miracle vaccines, treatments, and cures,¹⁴¹ it

136. News Release, Minn. Dep't of Health, *supra* note 118. Other reasons to store and use residual NBS include: (1) improving the quality of screening methods; (2) enabling “comparison and validation of new analytical methods”; (3) use in public health research; and (4) use in research to “enhance general medical knowledge.” OLSON & BERGER, *supra* note 107, at 10.

137. Even though these less-intrusive measures may be slightly more burdensome on the state, requiring parental consent “would arguably be less privacy invasive than conducting research without the parents’ knowledge.” KILAKKATHI, *supra* note 2, at 11; *see also infra* Part III.A (proposing an informed consent procedure for residual NBS use).

138. “[A] generally acknowledged component[] of a newborn screening system . . . includes . . . assessments of long-term benefits to individuals, families, and society.” Watson et al., *supra* note 14, at 15S.

139. The relevant statutes and case law are largely written in terms of protections and harms. *See, e.g.*, DEL. CODE ANN. tit. 20, § 3136 (2005) (authorizing isolation and quarantine during a public health *emergency*); Whalen v. Roe, 429 U.S. 589, 598 (1977) (asserting that the state has a “vital interest in controlling . . . *dangerous* drugs”) (emphasis added); *Jacobson*, 197 U.S. at 27 (concluding that communities have the right to protect themselves from disease based on “self-defense”).

140. *See, e.g.*, KILAKKATHI, *supra* note 2, at 11 (noting the “less grand benefits of screening” than those promised by the American College of Medical Genetics).

141. *See, e.g.*, Nic Fleming, *Cancer Cure ‘May Be Available in Two Years’*, TELEGRAPH, Sept. 19, 2007, <http://www.telegraph.co.uk/news/uknews/1563521/Cancer-cure-may-be-available-in-two-years.html> (discussing, in 2007, scientists’ assertions that “[c]ancer sufferers could be cured with injections of immune cells from other people within two years”).

is important to be cautious of allowing such speculative promises to justify intrusions on personal freedoms. Newborn screenings have been performed for over forty years¹⁴² and residual NBS have been used in a variety of studies,¹⁴³ but there have been few, if any, major “breakthroughs,” broadly felt public health benefits, or prevention of public health crises from research results.¹⁴⁴

A primary rationale for residual NBS research is to ensure the initial tests’ accuracy and to prevent false positives and false negatives.¹⁴⁵ However, quality assurance and accuracy research have not yielded such benefits. For example, one study concluded that there has been little change in the tests’ “positive predictive values” (PPV), which measure the probability that a patient with a positive test result *actually* has the indicated disorder.¹⁴⁶ Some states have a PPV of only 3%, meaning that 97% of infants who initially test positive *do not actually have the disease*.¹⁴⁷ Quality assurance research is important, but grand promises of medical breakthroughs should not be

142. Newborn screening programs began in the United States in the 1960s. KILAKKATHI, *supra* note 2, at 5.

143. See, e.g., V.W. Burse et al., *Preliminary Investigation of the Use of Dried-Blood Spots for the Assessment of in Utero Exposure to Environmental Pollutants*, 61 *BIOCHEMISTRY & MOLECULAR MED.* 236, 238 (1997) (concluding that NBS are a “valuable resource and cost-effective” source of information for a variety of different studies, such as the impact of prenatal exposure to environmental toxins); Karin B. Nelson et al., *Neuropeptides and Neurotrophins in Neonatal Blood of Children with Autism or Mental Retardation*, 49 *ANNALS NEUROLOGY* 597, 597 (2001) (using NBS to examine biological causes/origins of autism and mental retardation); Gary M. Shaw et al., *Genetic Variation of Infant Reduced Folate Carrier (A80G) and Risk of Orofacial and Conotruncal Heart Defects*, 158 *AM. J. EPIDEMIOLOGY* 747, 747 (2003) (analyzing residual NBS and finding “modest evidence for a gene-nutrient interaction” between a gene implicated in cleft palate, heart defects, and maternal intake of folic acid).

144. In fact, “[w]hen asked about other applications of newborn screening, [no] public health officials consulted . . . could offer examples of research projects that had yielded results aligned with the promises” made by the American College of Medical Genetics and Genomics, such as gaining a better understanding of diseases or developing a method for earlier interventions. KILAKKATHI, *supra* note 2, at 9, 11.

145. See *id.* at 11 (discussing states’ performance of “quality assurance studies”).

146. *Id.* at 10–11 (citing JoNel Aleccia, *Babies’ Blood Tests Can End in False-Positive Screening Scares*, MSNBC (May 9, 2011, 8:33 AM), http://www.today.com/id/42829175/ns/today-today_health/t/babiesblood-tests-can-end-false-positive-screening-scares/#.UifzROZQFlr).

147. *Id.* at 11.

used to justify a blanket waiver of informed parental consent.¹⁴⁸

The lack of significant findings or developments from residual NBS research raises serious questions about whether the proposed benefits of such research outweigh the potential risks and harms to individual rights and personal privacy. Because of the tenuous connections between protecting and promoting public health and NBS research, arguments attempting to justify a blanket waiver of consent for residual NBS use must fail.

2. Residual NBS Retention and Research: The Risks Are Real

In addition to the lack of significant benefits from residual NBS research, there are also real and legitimate risks of harm, particularly invasions to privacy. Risk-benefit ratios play an important role in precedent cases recognizing legitimate restrictions on individual rights.¹⁴⁹ It is therefore appropriate to analyze whether the alleged public health benefits of residual NBS research outweigh the potential risks. Residual NBS are stored in “DNA databanks,” and parents are concerned about potential genetic privacy violations¹⁵⁰ that can impact both the infant and his or her parents because certain genetic abnormalities of a child indicate the same abnormality in the parents.¹⁵¹ Fears of privacy breaches cannot be discounted or dismissed as “paranoi[d]” or “irrational.”¹⁵² Security breaches can and do occur at biological databanks, such as a laptop theft from the

148. See, e.g., *id.* (“[W]hile formulating screening tests and ensuring that existing tests meet certain quality standards are certainly beneficial applications of newborn screening, they seem to fall short of the stated promises of elucidating disease characteristics and generating earlier interventions.”).

149. *Whalen v. Roe*, 429 U.S. 589 (1977); *Jacobson v. Massachusetts*, 197 U.S. 11 (1905); *Compagnie Francaise de Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380 (1902); *NYC C.L.A.S.H., Inc. v. City of New York*, 315 F. Supp. 2d 461 (S.D.N.Y. 2004); *Wymyslo v. Bartec, Inc.*, 970 N.E.2d 898 (Ohio 2012).

150. KILAKKATHI, *supra* note 2, at 16–17.

151. For example, if an infant has Huntington’s disease, this indicates that at least one of his parents also has Huntington’s because it is an autosomal dominant disorder. U.S. Nat’l Library of Med., *Huntington Disease*, GENETICS HOME REFERENCE (September 9, 2013), <http://www.ghr.nlm.nih.gov/condition/huntington-disease>.

152. Attempts at discounting these fears have been made before. See Taralyn Tan, *Newborns’ DNA: Don’t Deny Scientists This Useful Resource*, GENETIC ENG’G & BIOTECH. NEWS, <http://www.genengnews.com/gen-articles/newborns-dna-don-t-denyscientists-this-useful-resource/4377/> (last visited Oct. 17, 2013). Others note though that “privacy breaches [are] not just a hypothetical problem.” KILAKKATHI, *supra* note 2, at 16.

Cord Blood Registry, the largest stem cell bank in the world.¹⁵³

Some argue that these privacy concerns are unfounded because the samples can be de-identified before research use and thus do not require the additional protections typically afforded to human subjects research under the Common Rule.¹⁵⁴ These arguments, however, are unsatisfactory because although de-identified samples are not *directly* identifiable, they are not completely “anonymous,” and research shows that de-identified samples *can* be linked back to the individual.¹⁵⁵ Despite assurances that genetic data is de-identified and confidential, “[s]cientists have been aware for years of the possibility that coded or ‘anonymized’ sequenced DNA *may be more readily linked to an individual* as genetic databases proliferate.”¹⁵⁶ In one study, researchers were able to “accurately and robustly determine” whether a specific individual’s DNA was present in a “complex genomic DNA mixture.”¹⁵⁷

Given the misunderstood definitions of de-identification, arguments that the de-identification process eliminates the potential for privacy breaches and dissemination of personal biological and genetic information do not pass scientific muster.¹⁵⁸

153. KILAKKATHI, *supra* note 2, at 16.

154. Defendants’ Motion to Dismiss or for Summary Judgment Based on Mootness at 6, *Beleno v. Tex. Dep’t of State Health Servs.*, No. SA-09-CA-0188-FB (W.D. Tex. dismissed Dec. 14, 2009), 2009 WL 5072237 (stating that under TEX. HEALTH & SAFETY CODE § 33.018, de-identified information “may be released without consent” when it is being disclosed for a number of purposes, including research approved by the Institutional Review Board); *see also* sources cited *supra* note 107.

155. Rothstein, *supra* note 107, at 3, 5–6. “Identifiability exists on a continuum” and is affected by the particular de-identification technique used. *Id.*

156. Amy L. McGuire & Richard A. Gibbs, *No Longer De-Identified*, 312 SCI. 370, 370 (2006) (emphasis added).

157. Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, PLOS GENETICS, Aug. 29, 2008, at 1, 1, available at <http://www.plosgenetics.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pgen.1000167&representation=PDF>; *see also* Melissa Gymrek et al., *Identifying Personal Genomes by Surname Inference*, 339 SCI. 321, 323–24 (2013) (reporting results of a study in which researchers were able to determine the identities of fifty study participants from genetic information that had supposedly been de-identified).

158. *See* Rothstein, *supra* note 107, at 3. Researchers have been able to take “seemingly anonymous DNA database entries . . . and specifically identify the persons who are the subjects of the information even though the DNA information” had been de-identified. Bradley Malin & Latanya Sweeney, *Re-Identification of DNA Through an Automated Linkage Process*, PROC. J. AM. MED. INFO. ASS’N SYMP. 423, 423 (2001). Even if complete and irreversible de-identification were possible, non-consensual use of an individual’s genetic in-

The ambiguity of the term “de-identification” was noted by the Plaintiffs in *Bearder*, who stated that “it is not so clear what [the Minnesota Department of Health (MDH)] means when they say that the blood samples and test data are ‘de-identified.’”¹⁵⁹ In response to the Plaintiffs’ request for documents detailing MDH’s de-identification procedure, the Defendants replied that “[n]o documents exist showing MDH processes of de-identification and reidentification,” indicating that there is no established de-identification procedure and that the process and standards “vary from project to project and are subject to *subjective* standards.”¹⁶⁰ Given that it is possible to re-identify de-identified samples, the Common Rule protections—including informed consent¹⁶¹—should apply to residual NBS because the Rule only exempts information that “cannot be identified, directly or through identifiers linked to the subjects.”¹⁶²

It is important to recognize that the potential privacy harms are both tangible and intangible. Many are primarily concerned about employment and/or insurance discrimination, but for others the mere fact that one’s privacy has been violated is viewed as “an intrinsic harm separate from discrimination.”¹⁶³ Given the uncertain benefits and the real and legitimate risks of harm, informed consent and transparency are even *more* important because of the inherent value many place on their right to privacy and their desire to control what happens to their infant’s residual NBS.¹⁶⁴ Indeed, many parents would consent to residual use of their infant’s NBS; they simply

formation is still questionable and raises issues regarding the *inherent* harms of disregarding autonomy, individual rights, and privacy rights. Analysis of the issue if complete de-identification were possible, however, is beyond the scope of this particular paper.

159. Plaintiffs’ Memorandum of Law at 33, *Bearder v. State*, 806 N.W.2d 766 (Minn. 2011) (No. 27-CV-09-5615), 2009 WL 5427609.

160. *Id.* (emphasis added).

161. “[N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.” 45 C.F.R. § 46.116 (2012).

162. 45 C.F.R. § 46.101 (2012).

163. KILAKKATHI, *supra* note 2, at 17–18.

164. “It’s respect. It should be an opt-in. I give my permission to do this.” Rothwell et al., *supra* note 11, at 1307 (quoting focus group participants’ thoughts on research with residual NBS).

want to be *asked* and *informed* first.¹⁶⁵ As one parent succinctly stated: “I want to have the choice.”¹⁶⁶

B. RISK-BENEFIT RATIOS: WHO *REALLY* BENEFITS?

If residual NBS research *is* beneficial, it must be determined who will actually benefit and whether the benefits and burdens are fairly distributed.¹⁶⁷ Scientific research using biological and genetic information from any source can benefit society as a whole,¹⁶⁸ but speculative promises are inadequate to justify nonconsensual use of a person’s genetic material.¹⁶⁹ If new diseases are discovered or new treatments developed through NBS research there is no guarantee that the majority of the public will benefit. The unclear distribution of benefits contrasts to the actual, broadly felt public health benefits of policies such as smoking bans¹⁷⁰ and mandatory vaccinations,¹⁷¹ which can—and do—benefit the greater public. It is likely that residual NBS research is, at least in part, facilitated by private financial interest.¹⁷²

We no longer live in the era of Jonas Salk, who, when asked who owned the patent to his newly developed polio vaccine, responded, “Well, the people, I would say. There is no pa-

165. “What’s important is just giving people a choice. I don’t like not having a choice and that’s what bothers me.” *Id.*

166. *Id.*

167. The Belmont Report obligates the just allocation of benefits and burdens in human subject research. The Belmont Report, *supra* note 109.

168. See, e.g., REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* 2 (2010) (discussing the use of Lacks’ cells to facilitate “some of the most important advances in medicine: the polio vaccine, chemotherapy, cloning, gene mapping, in vitro fertilization”).

169. See KILAKKATHI, *supra* note 2, at 11 (suggesting that “the ‘public health benefits’ cited by . . . public health officials and patients’ groups may not live up to their promise”).

170. *Smoking Bans in Bars*, *supra* note 133 (“Bans on smoking in bars and restaurants . . . reduce tobacco-related illnesses . . .”).

171. See, e.g., *Community Immunity*, *supra* note 128 (explaining the concept of herd immunity).

172. “Part of the issue is that some parents are concerned that the state or private companies could profit from the use of their children’s blood samples.” News Release, Johns Hopkins, *supra* note 71 (quoting Michelle Lewis) (internal quotation marks omitted); see also Aaronson, *supra* note 91 (quoting attorney Jim Harrington, who, in response to the possibility that the Texas Department of State Health Services sold and/or traded NBS to commercial entities, stated that “[i]t’s one thing to opt in to a research program that’s non-profit; it’s another thing to have your DNA or your kid’s DNA used by a company to make millions of millions of dollars”).

tent. Could you patent the sun?”¹⁷³ Salk’s response suggests that benefitting “the public as a whole” must at times take precedence over innovators’ rights.¹⁷⁴ But times have changed, and today a major driver of innovation—particularly in medicine—is profit potential,¹⁷⁵ and both states and researchers profit from residual NBS research.¹⁷⁶ Profitability and promoting health and well-being do not necessarily go hand-in-hand. When courts have recognized justifiable restrictions on individual rights for public health purposes, the primary reasons for the restrictions have been to protect the public from *imminent*¹⁷⁷ or *well-evidenced* long-term harms.¹⁷⁸ Unlike NBS research, neither the state nor private entities had secondary, profit-driven motives in precedent case law.¹⁷⁹

The potential for profit incentives to play a role in NBS research raises questions about whether the promised benefits (new discoveries, treatments, etc.) will be available to “the public.” Providing broad public access to screenings and treatments to promote public health is generally *not* a highly profitable enterprise,¹⁸⁰ and despite a history of non-profit provision of care,

173. Krysta Kauble, Comment, *Patenting Everything Under the Sun: Invoking the First Amendment to Limit the Use of Gene Patents*, 58 UCLA L. REV. 1123, 1125 (2011).

174. *Id.*

175. See *id.* at 1131–32 (discussing the practice of granting patents on “product[s] of nature,” and the increasing “financial interest in gene patents”). *Moore v. Regents of the University of California* is another example of issues arising from profit-driven medical research. The case involved a doctor using a patient’s tissues without consent for research resulting in a patent that had a predicted profit potential of \$3 billion. 51 Cal. 3d 120, 174 (Cal. 1990).

176. See Aaronson, *supra* note 91 (discussing the Texas Department of State Health Services’ trade of NBS for expensive lab supplies).

177. A highly contagious disease would be considered an imminent harm. See *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905); *Compagnie Francaise de Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380, 381 (1902).

178. See *Whalen v. Roe*, 429 U.S. 589, 597–98 (1977) (upholding a law meant to prevent misuse of dangerous drugs); *NYC C.L.A.S.H., Inc. v. City of New York*, 315 F. Supp. 2d 461, 466 (S.D.N.Y. 2004) (noting “mounting scientific evidence” linking ETS “to serious health risks to non-smokers”); *Wymyslo v. Bartec, Inc.*, 970 N.E.2d 898, 904–05 (Ohio 2012), *reconsideration denied*, 971 N.E.2d 962 (Ohio 2012) (“[S]tudies have conclusively shown that exposure to secondhand smoke . . . causes illness and disease . . .”).

179. On the contrary, many business owners feared smoking bans would decrease their profits. See *Wymyslo*, 970 N.E.2d at 915 (rejecting appellants’ claim regarding a decline in gross sales).

180. For example, pharmaceutical companies have little incentive to produce the flu-shot or other low-cost and therefore lower-profit vaccines, preferring to invest in high-cost drug development. The highest grossing vaccine has yearly sales of about \$1 billion, whereas a drug for diabetes can have annual

our health care system has become increasingly commercialized.¹⁸¹ States and researchers assure the public that NBS research will result in beneficial medical advancements, but they do not further promise that these benefits will actually be available to society as a whole. For example, if an effective treatment was developed for a particular disease using NBS, would states subsidize this treatment to make it affordable, or would it be prohibitively expensive, preventing many from reaping the benefits of NBS research? It seems unlikely states will—or even can—make such promises. Thus it may be naïve to assume NBS research will provide the broad “public” benefits that have been promised, given today’s profit-driven climate.¹⁸² And although a public health benefit need not be universally experienced by every individual, the ability to benefit should not be dependent on ability to pay.¹⁸³

Justifying privacy infringements as serious as those involving an individual’s genetic information based on a public health promotion argument could justify far too many other infringements and make it difficult to draw lines in the future. For example, if states can justify NBS use for public health-promoting

sales of more than \$7 billion. Tim Krohn, *Sick Days, Manufacturing Vaccine Equal Bad Business*, FREE PRESS, Jan. 9, 2013, <http://mankatofreepress.com/local/x964869559/Krohn-Sick-days-manufacturing-vaccine-equal-bad-business>.

181. For a discussion of a non-profit versus for-profit health care system, see Claire Andre & Manuel Velasquez, *A Healthy Bottom Line: Profits or People?*, 1 ISSUES IN ETHICS, no. 4, Summer 1988, available at <http://www.scu.edu/ethics/publications/ie/v1n4/healthy.html>; see also Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 HEALTH AFFAIRS 622, 622 (2005) (noting that pharmaceutical companies are driven by profits because they are “businesses, not public health agencies”).

182. It could be argued that curing a previously incurable disease, no matter how small the affected population, justifies nonconsensual NBS research. However, it would be inappropriate to use the state’s police powers to justify such intrusion on individual rights and autonomy. Although we may wish that the state would do so, it has no obligation to eradicate all potential or existing diseases. In a public health context, police powers are invoked when necessary to protect the *broader public*, which by definition requires a benefit to more than just a small number of individuals. Indeed, “a principal aim of public health is to achieve the greatest health benefits for the *greatest number of people*.” PUBLIC HEALTH LAW AND ETHICS: A READER 14 (Lawrence O. Gostin ed., 2d ed. 2010) (emphasis added).

183. The very nature of a public health system is to ensure that persons in need are *not* denied care based on ability to pay. See, e.g., *The Ethics of Health Care Reform: Issues in Emergency-Medicine—An Information Paper*, AM. COLL. EMERGENCY PHYSICIANS, <http://www.acep.org/Content.aspx?id=80871> (last visited Oct. 17, 2013) (stating that public health insurance programs exist, in part, because “[w]e are unwilling to deny health care to other persons in need”).

research, perhaps they could also justify mandatory organ procurement from all deceased citizens—with or without consent. There is much stronger evidence of the benefits from organ donation than from residual NBS research; organ donations can—and do—save lives,¹⁸⁴ which contrasts with the mere *assumptions* that NBS research will lead to beneficial discoveries and developments.¹⁸⁵ Using similar justifications, states could attempt to mandate all types of research participation, such as clinical trials for new drugs that could, if approved, benefit the public health.¹⁸⁶

The value American society places on autonomy, personal privacy, and the right to control one's own body requires the conclusion that the potential benefits of residual NBS research do not outweigh its possible tangible¹⁸⁷ and intangible¹⁸⁸ harms. The state's interest in promoting public health is neither an adequate nor compelling enough justification to allow a blanket waiver of informed parental consent. This conclusion does not, however, require states to end residual NBS use altogether. Instead, states must develop and implement informed consent policies and increase the transparency of their residual NBS policies. Part III proposes possible mechanisms for implementing and improving an informed consent process.

184. Over 28,000 organ transplants were performed in 2012. *Organ Donation*, DONATE LIFE AM., <http://donatelife.net/understanding-donation/organ-donation/> (last updated Mar. 2013). Approximately 75% of patients receiving a heart transplant survive at least five years post-transplant. Nat'l Heart, Lung, & Blood Inst., *What Is a Heart Transplant?*, DEP'T HEALTH & HUMAN SERVS. (Jan. 3, 2012), <http://www.nhlbi.nih.gov/health/health-topics/topics/ht/>.

185. See *supra* notes 142–44 and accompanying text.

186. These justifications could also extend to contexts outside of public health. Justifying infringements on the individual rights of a vast majority of the population (i.e., all newborn infants and their parents) to benefit very few individuals could permit the state to justify almost any action, as long as it protects/benefits even just one individual. For example, would we want the state to justify mass unwarranted searches and seizures of homes based on the premise that 1 in 500 will turn up an illegal activity (if we assume catching criminals is in the public's interest)? Although this analogy is not exact, it accurately exposes the risks and benefits behind the “common good” argument.

187. “Tangible harms” refer to risks of privacy/confidentiality breaches and the harms that could result if a biobank security system were breached and resulted in dissemination of a person's genetic information.

188. “Intangible harms” is used to refer to the inherent disrespect felt by individuals who were not given the opportunity to consent to the state's use of their child's genetic information.

III. DEVELOPMENT AND IMPLEMENTATION OF ADEQUATE INFORMED CONSENT POLICIES FOR THE RETENTION AND USE OF RESIDUAL NBS

Good intentions and speculative benefits do not give a state an absolute and un-tempered power to intrude on individual rights.¹⁸⁹ When restricting individual liberties, a state should have “clear and convincing evidence”¹⁹⁰ that the infringements will achieve its goal(s) and should use the “least restrictive means” possible to achieve these goals.¹⁹¹ In the context of residual NBS storage and use, states have failed on both accounts, most importantly the least restrictive means requirement. Research to advance medical knowledge and develop new treatments is important, but it need not be achieved through the surreptitious attainment of genetic material.

New parents are, in many ways, a captive audience. New parents may feel overwhelmed after their child’s birth,¹⁹² but there are still many opportunities to discuss what they want to do with their child’s residual NBS.¹⁹³ Part A proposes a model

189. See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1905) (recognizing “a sphere within which the individual may . . . dispute the authority of any human government . . . to interfere with the exercise of that will”).

190. See, e.g., DEL. CODE ANN. tit. 20, § 3136 (2005); HAW. REV. STAT. § 325–8(g) (West 2008); IND. CODE § 16-41-9-1.5 (LexisNexis 2011).

191. Many states have “least restrictive means necessary” requirements in their quarantine statutes. See, e.g., ARIZ. STAT. ANN. § 36-788 (2009); DEL. CODE ANN. tit. 20, § 3136; HAW. REV. STAT. § 325–8(b); MINN. STAT. ANN. § 144.419 (West 2011); N.J. STAT. ANN. 26:13-15 (West 2007); OR. REV. STAT. § 433.128 (West 2011). For further commentary on the importance of a due process procedure to govern quarantine decisions, see Gregory P. Campbell, *The Global H1N1 Pandemic, Quarantine Law, and the Due Process Conflict*, 12 SAN DIEGO INT’L L.J. 497 (2011).

192. See KILAKKATHI, *supra* note 2, at 13 (acknowledging the sometimes-chaotic atmosphere after childbirth).

193. These opportunities are present during pre-natal visits and post-partum care/hospitalization. The majority of pregnant women in the United States receive “adequate” prenatal care, as defined by the Adequacy of Prenatal Care Utilization (APNCU) Index, which involves more than eleven prenatal care visits. See Geraldine Oliva et al., *Birth Data Analysis & Presentation System Manual*, EPIBC 2005 i-28 (2005), available at http://fhop.ucsf.edu/fhop/docs/pdf/manuals/epibc05/EpiBC05man_all.pdf; America’s Health Rankings, *USA Prenatal Care (1990–2011)*, UNITED HEALTH FOUND. (2013), <http://www.americashealthrankings.org/All/PrenatalCare/2012> (indicating that roughly 70% of women throughout the U.S. receive adequate prenatal care as defined by the APCNU Index). After giving vaginal birth, most women remain in the hospital for two days, and Congress has enacted legislation requiring group health plans to cover a minimum 48-hour post-partum hospital stay. See 42 U.S.C. § 300gg-25 (2006); Committee on Fetus and Newborn, *Policy Statement—Hospital Stay for Healthy Term Newborns*, 125 PEDIATRICS 405, 405

that states should consider when developing and implementing policies governing informed consent for residual NBS use. Parts B and C discuss different times when informed consent may be sought. States and public health researchers may resist such policy changes, claiming they are too burdensome to implement. States can certainly choose to maintain their current policies (or lack thereof), but given the recent litigation in Texas and Minnesota and the increasing publicity of state storage and use of residual NBS and other genetic material, failing to make changes increases the likelihood of future litigation.

A. THE INADEQUACIES OF AN OPT-OUT MODEL AND THE NEED FOR AN OPT-IN PROFESSIONAL “REQUESTOR” POLICY

States should implement “opt-in” rather than “opt-out” programs because opt-in policies promote information-sharing and provide a better opportunity for parents to make informed decisions.¹⁹⁴ An opt-out system relies on *presumed* consent—that parents agree to the storage and use of their child’s residual NBS unless they explicitly refuse.¹⁹⁵ A potential problem with opt-out systems is that they “require[] that health care providers give parents more information than they currently do”¹⁹⁶ about the initial screening and the residual storage and use of NBS.¹⁹⁷ Therefore, an opt-out system “is not a true model of consent because it does not require any form of consent; instead . . . [it] functions as a *substitute* for consent.”¹⁹⁸ Assuming that silence is equivalent to consent is a problematic, and at times mistaken, assumption to make, particularly given the ev-

(2010), available at <http://pediatrics.aappublications.org/content/125/2/405/full.pdf>; Employee Benefits Security Administration, *Fact Sheet—Newborns’ and Mothers’ Health Protection Act*, U.S. DEP’T LABOR, <http://www.dol.gov/ebsa/newsroom/fsmhafs.html#UOiZQW9kw0U> (last visited Oct. 17, 2013).

194. See KILAKKATHI, *supra* note 2, at 24–25.

195. Ross, *supra* note 5, at 313.

196. *Id.*

197. See KILAKKATHI, *supra* note 2, at 12 (noting that many jurisdictions which allow parents to refuse the initial screenings do not require any patient-provider communication prior to the screening). Additionally, providers may be unaware that refusal is an option, and thus do not inform parents of their right to opt-out. See *Real Life Stories: Taking Baby DNA*, CITIZENS’ COUNCIL ON HEALTH CARE (Mar. 26, 2009), <http://www.cchfreedom.org/pdf/RealLifeStories%20BabyDNA-1FINAL.pdf> (“Our nurses didn’t even know we could opt out, or that any collection was going to the government.”).

198. KILAKKATHI, *supra* note 2, at 24 (emphasis added).

idence that many parents are ill-informed about residual storage and use policies.¹⁹⁹

An “opt-in” consent procedure is preferable because it requires parents to provide “affirmative consent” to allow residual NBS storage and use.²⁰⁰ An opt-in policy requires knowledge and information on *both* sides: the “requestor” of consent must know the procedures for obtaining consent and what storage and use of residual NBS entails, and this information must be provided to parents before they can consent and “opt-in” to residual storage and use. This model increases the exchange of important information and requires improved training of the medical professionals obtaining consent.²⁰¹ An opt-in program further ensures that parents have the opportunity to ask questions and address their concerns before deciding whether to consent to research using their newborn’s residual NBS. Indeed, “the only way to be sure that someone is *truly* consenting . . . is to obtain his or her *affirmative* consent.”²⁰²

An opt-in model is particularly preferable in light of the unclear risk-benefit ratio of residual NBS research.²⁰³ In her discussion of opt-in versus opt-out consent procedures for the initial NBS screenings, Doctor Lainie Friedman Ross posits that while opt-out procedures for high benefit-risk ratio programs may be justifiable, when the benefit-risk ratio is unclear, an opt-in procedure is preferable because it “may provide the best way to balance respect for parental autonomy and the promotion of children’s health.”²⁰⁴ Because residual NBS research has an unclear risk-benefit ratio, it is better suited for an opt-in policy, which will promote a balance between respect for parental autonomy and public health promotion.²⁰⁵

To facilitate the development of improved informed consent policies, a useful model for states to follow is a “requestor” model, which has been successfully used as part of the organ

199. *Id.*

200. *Id.* (emphasis added).

201. Currently, many medical professionals, such as obstetrical physicians and nurses, as well as pediatricians, lack adequate information and training about residual NBS storage and use. *See id.* at 24; Ross, *supra* note 5, at 319.

202. KILAKKATHI, *supra* note 2, at 24 (emphasis added).

203. *See supra* Part II for a discussion of the lack of significant benefits from residual NBS research and the concomitant privacy risks and liberty infringements of residual NBS use without parental consent.

204. Ross, *supra* note 5, at 320.

205. *Id.*

procurement process.²⁰⁶ Organ procurement organizations (OPOs) have implemented requestor programs in order to increase the number of available organs.²⁰⁷ The United States organ donation system operates under an “opt-in” model: the donor himself can opt to be a donor prior to death²⁰⁸ or, if the deceased did not indicate his preference, the potential donor’s family is given the option of donation.²⁰⁹ The requestor model is a multi-disciplinary team approach to discussing and requesting organ donation from deceased individual’s family members.²¹⁰ Although an organ procurement requestor’s role begins at the *end* of life, an analogous requestor model can be used at the *beginning* of life to facilitate informed parental consent in procuring residual NBS for research. The circumstances in which they are asked may be different, but what is being asked of family members of the deceased or parents of a newborn is quite similar—whether they wish to donate their relative’s personal biological material for the purpose of promoting the health and well-being of others.²¹¹

206. See, e.g., CAITLIN CARROLL ET AL., U.S. DEP’T OF HEALTH & HUMAN SERVS., ROLES AND TRAINING IN THE DONATION PROCESS: A RESOURCE GUIDE, at Preface (2000), available at <http://www.wsha.org/files/62/RolesAndTrainingGuide.pdf> (discussing 42 C.F.R. Part 482, which “requires that those who [a] hospital designates to initiate donation requests receive training offered or approved by the [organ procurement organization]”).

207. *Id.*

208. The Uniform Anatomical Gift Acts of 1967 and 1987 established the right to donate all or part of one’s body upon death. UNIF. ANATOMICAL GIFT ACT § 1–2 (1987). Each state has a donor registry where individuals can sign up to be organ donors. See U.S. Dep’t of Health & Human Servs., *State Organ and Tissue Donor Registries*, ORGANDONOR.GOV, <http://organdonor.gov/becomingdonor/stateregistries.html> (last visited Oct. 17, 2012).

209. 42 U.S.C. § 1320b-8 (2006) (allowing hospitals to participate in organ procurement if the “hospital establishes written protocols for the identification of potential organ donors that assure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline”); see also UNIF. ANATOMICAL GIFT ACT § 3 (1987) (“Any member of the following classes . . . may make an anatomical gift of all or a part of the decedent’s body for an authorized purpose, unless the decedent, at the time of death, has made an unrevoked refusal to make that anatomical gift”); CARROLL ET AL., *supra* note 206, at 14–15 (providing an overview of legislation relevant to the organ donation process).

210. CARROLL ET AL., *supra* note 206, at 17.

211. Organ donation has clear health benefits—in 2012, 22,187 transplants were performed using deceased donor organs. U.S. Dep’t of Health & Human Servs., *Deceased Donor Transplants in the U.S. by State*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/latestData/step2.asp> (select Choose Category “Transplant” and select Choose

Several studies support the effective use of a multidisciplinary “team” approach in obtaining consent for organ donation²¹² that could be applied NBS donation. The model involves three roles which, although distinct, must collaborate for the requestor model to be successful. The three roles are (1) coordinator; (2) requestor; and (3) supporter.²¹³ The coordinator facilitates the collaboration of everyone involved in the process, ensuring that it is “carried out in accordance with relevant policies and protocols.”²¹⁴ The requestor has the important job of empowering the parents to make decisions—he or she “is the individual who will offer the option of donation . . . or discuss donation with” the newborn’s parents.²¹⁵ The supporter’s job is to assist everyone in the process—the coordinator, the requestor, and the infant’s parents.²¹⁶

Adequate training is essential to ensure effective and successful use of the team approach. Training is particularly important for requestors, whose role brings them into intimate contact with parents during a momentous—and often overwhelming—time in their lives and thus requires patience, understanding, and respect. A requestor could be an existing health care professional, such as a doctor, nurse, or social worker, or hospitals could hire and train a person whose sole job is to be a requestor. The model used by each hospital may differ, as larger hospitals with more births may benefit from having employees whose sole job is to request NBS donations. Some of the necessary components of a successful and respectful donation request policy include²¹⁷: (1) understanding families in the post-childbirth stage; (2) maintaining respect for the family; (3) developing communication skills; (4) getting to know the parents; (5) assessing family dynamics and modifying approaches; (6) being sensitive to cultural, religious, and spiritual influences;²¹⁸ and (7) providing ongoing support and infor-

Organ “All,” follow “Deceased Donor Transplants by State”) (data last updated Oct. 11, 2013).

212. CARROLL ET AL., *supra* note 206, at 17.

213. *Id.* at 17–18.

214. *Id.* at 18.

215. *Id.*

216. *Id.*

217. Adapted from *id.* at 27–29.

218. Successfully fulfilling numbers (5) and (6) may require matching a requestor with the parents, because “people tend to respond more positively to individuals that they feel they can trust or with whom they can identify.” *Id.* at 29. This can involve having a requestor that speaks the parents’ native language, understands or practices the parents’ religion, and is of the same eth-

mation. Regardless of the method chosen—using an existing employee to act as a requestor or hiring an employee whose sole role is to be a requestor—all health care providers who interact with parents—both pre-natal and post-natal—should receive training and education on residual NBS policies, as there is currently a general lack of knowledge about this topic among the medical profession.²¹⁹

Storage and use of residual NBS can be a complicated topic to understand and parents may have numerous questions. Therefore, the requestor must be willing and able to spend considerable time with parents to ensure they have ample opportunity to ask questions and understand the storage process and what their child's NBS may be used for during research.²²⁰

State policies should allow parents to change their minds and later request that their child's stored NBS be destroyed. Requestors must have adequate training in and understanding of the process of de-identification or anonymization of NBS, and states should enact policies that require anonymization, a process that strips the blood sample of all identifiers so that the sample is—as much as is scientifically possible—anonymous and nearly impossible to trace back to the particular infant.²²¹

B. PRE-NATAL CARE DISCUSSIONS AND CONSENT

The ideal scenario is to begin discussions about residual NBS storage and use during pre-natal care. The requestor, along with pre-natal care providers—who should receive specific training and education on their state's newborn screening program and NBS retention policies—could introduce the idea of residual NBS research to the parent(s) at prenatal care visits. Alternatively, separate appointments could be made for the sole purpose of discussing residual NBS use to ensure the requestor has adequate time to explain the policies and proce-

nic, racial, or cultural background as the parents. *Id.* at 29. Using “like” requestors is associated with improved donation rates among both African American and Hispanic individuals. *See, e.g.*, Susan L. Bratton et al., *Pediatric Organ Transplantation Needs: Organ Donation Best Practices*, 160 ARCHIVES PEDIATRIC & ADOLESCENT MED. 468, 469 (2006); JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., HEALTH CARE AT THE CROSSROADS: STRATEGIES FOR NARROWING THE ORGAN DONATION GAP AND PROTECTING PATIENTS 8, 13, 18 (2004), available at http://www.jointcommission.org/assets/1/18/organ_donation_white_paper.pdf.

219. *See* KILAKKATHI, *supra* note 2, at 24; Ross, *supra* note 5, at 319.

220. CARROLL ET AL., *supra* note 206, at 27.

221. OLSON & BERGER, *supra* note 107, at 31–32.

dures and to allow the parents to ask questions. It should be clear to parents that they have the option to refuse residual NBS retention and use. The pre-natal discussions would be ongoing and final decisions would not be made nor consent given until after the child's birth. Beginning the discussion as early as possible allows parents to think through their decisions and to ask questions. This method recognizes that informed consent should be more than a signature on a page—it should be a *process* during which the consenter comes to know and truly understand what it is he or she is consenting to.

C. POST-NATAL DISCUSSIONS AND CONSENT

The unfortunate reality is that not all women receive prenatal care²²² and thus pre-natal discussions will not always be possible. In such situations, after the woman has given birth and recuperated, but prior to discharge, a trained requestor should engage the parent(s) in a discussion about storage and residual use. The conversation should not occur immediately prior to discharge, as the woman is likely receiving other information at this time and may be in a hurry to get out of the hospital. In a rush to complete a mountain of discharge paperwork, the parent(s) may make hurried judgments that are not truly informed and well thought-out. All parents should be given time to think about their decision if they are unsure—residual NBS should not be disseminated for research purposes for at least one month after the infant is born. Requestors could follow-up with a phone call to discuss the parent's decision, an appointment could be made, or the issue could be re-visited at the newborn's one-month physical. Parents should not feel rushed into the decision—if they are not ready to provide consent, they should have additional time.

Contrary to some arguments, parental consent is possible for residual NBS research. The costs and burdens of an opt-in, consensual procedure are inadequate justifications to completely forego parental consent. In an age of impressive advancements in genomic medicine, we must be aware of potential privacy issues and draw lines early and often between legitimate and illegitimate use of our genetic information without consent.

222. In 2010, approximately 6.2% of mothers received late (defined as third-trimester or later) or no prenatal care. CHILD TRENDS DATA BANK, LATE OR NO PRENATAL CARE: INDICATORS ON CHILDREN AND YOUTH app. 1, at 9 (2012), available at http://www.childtrends.org/wp-content/uploads/2012/11/25_Prenatal_Care.pdf.

As a society, we cannot allow administrative costs or burdens to justify infringements on individual rights, parental rights, and genetic privacy. Protections and safeguards *are* possible—we simply must be willing to spend the time and resources to develop and implement them.

CONCLUSION

The government's interest in and obligation to promote public health is historically, legally, and socially acknowledged. This interest cannot, however, justify non-consensual use of residual NBS. Although residual NBS research has the potential to promote public health through discovery of new diseases and treatment, such benefits have thus far been tenuous at best. A state's police power is not absolute and cannot be invoked to justify a blanket waiver of parental consent for residual NBS use. To avoid future litigation, states must address their inadequate or altogether non-existent policies governing residual NBS retention and use. These policies should include a robust informed consent procedure that will increase transparency and seek a balance between individual rights and the importance of public health research that aims to detect new conditions, develop new therapies, and eradicate diseases.