

12-1-2016

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### Recommended Citation

Tufik Y. Shayeb, *Informed Consent for the Use and Storage of Residual Dried Blood Samples from State-Mandated Newborn Genetic Screening Programs*, 64 Buff. L. Rev. 1017 (2016).

Available at: <https://digitalcommons.law.buffalo.edu/buffalolawreview/vol64/iss5/3>

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# Informed Consent for the Use and Storage of Residual Dried Blood Samples from State-Mandated Newborn Genetic Screening Programs

TUFIK Y. SHAYEB†

## INTRODUCTION

Every year, approximately four million newborn infants have their blood collected and screened for metabolic and genetic disorders.<sup>1</sup> The clinical and predictive value of many of these tests is uncertain, casting some doubt on the practical value of mandatory, non-consensual screening in general.<sup>2</sup> Nevertheless, state health departments in the United States mandate newborn screening,<sup>3</sup> and this practice is firmly rooted in the widespread belief that the benefits of screening for genetic disease in newborns significantly outweigh the costs.<sup>4</sup> Newborn screening

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1. See Jennifer Kraszewski et al., *Legal Issues in Newborn Screening: Implications for Public Health Practice and Policy*, 121 PUB. HEALTH REP. 92 (2006).

2. See generally *id.*; Bradford L. Therrell, Jr., *U.S. Newborn Screening Policy Dilemmas for the Twenty-First Century*, 74 MOLECULAR GENETICS & METABOLISM 64 (2001).

3. See Therrell, *supra* note 2, at 67.

4. See INST. OF MED. OF THE NAT'L ACADS., CHALLENGES AND OPPORTUNITIES IN USING RESIDUAL NEWBORN SCREENING SAMPLES FOR TRANSLATIONAL RESEARCH: WORKSHOP SUMMARY 5–8 (2010), <http://www.ncbi.nlm.nih.gov/books/NBK52731/> (covering the benefits of newborn screening in Chapter 2); Bradford L. Therrell et al., *Status of Newborn Screening Programs in the United States*, 117 PEDIATRICS S212, S213 (2006).

programs regularly generate a cache of residual dried blood samples that are sometimes stored for varying periods of time.<sup>5</sup> In some states, those residual samples have been utilized in unrelated research and even shared with third-parties without the informed consent of the families of the donor infants.<sup>6</sup>

As a result of this practice, some states have seen litigation from the families of newborn infants challenging the constitutional boundaries of the non-consensual taking of blood samples, the utilization of those samples in unrelated research studies, and the disclosure of those samples to unrelated third-parties.<sup>7</sup> Some advocates and commentators have called for a national, uniform solution to this dilemma, with a frequently cited emphasis on requiring informed consent.<sup>8</sup> This Article, however, argues that while informed consent should be required for third-party disclosure of blood samples, non-consensual use of those samples in research studies done for the benefit of advancing the state's screening program likely does not exceed a state's given constitutional authority.<sup>9</sup>

Part I of this Article briefly surveys the background of newborn genetic screening, including the rise of mandatory

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5. Therrell, *supra* note 2, at 67; see generally Adam Doerr, *Newborn Blood Spot Litigation: 70 Days to Destroy 5+ Million Samples*, GENOMICS L. REP. (Feb. 2, 2010) available at <http://www.genomicslawreport.com/index.php/2010/02/02/newborn-blood-spot-litigation-70-days-to-destroy-5-million-samples/> (last accessed Oct. 6, 2010).

6. See Adam Doerr, *Newborn Blood Spot Litigation: 70 Days to Destroy 5+ Million Samples*, GENOMICS L. REP. (Feb. 2, 2010), <http://www.genomicslawreport.com/index.php/2010/02/02/newborn-blood-spot-litigation-70-days-to-destroy-5-million-samples/> (last visited Oct. 6, 2010).

7. See, e.g., *Higgins v. Tex. Dep't of Health Servs.*, 801 F. Supp. 2d 541 (W.D. Tex. 2011); *Bearder v. State*, 806 N.W.2d 766 (Minn. 2011); First Amended Complaint, *Beleno v. Tex. Dep't of State Health Servs.*, No. SA-09-CA-0188-FB, 2009 WL 5072239 (W.D. Tex. Sept. 29, 2009).

8. See generally Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 J. AM. MED. ASS'N. 1786 (1995); see also *infra* Part III.

9. See *infra* Part I.

screening programs, the current status of such programs in the United States, and the growing trend of residual dried blood sample biobanking.<sup>10</sup> Part II discusses several high-profile lawsuits that explored the major legal issues implicated in mandatory, nonconsensual testing and research.<sup>11</sup> Finally, Part III of this Article examines potential enforcement mechanisms for establishing uniform standards and sets forth the argument that while informed consent should be required prior to third-party sample sharing, it need not be required for state-run research activities aimed at improving a state's newborn genetic screening program.<sup>12</sup> This Article ultimately concludes that the superior approach to addressing the concerns raised below is to allow a state to maximize its constitutional authority while exercising such authority in a restrained manner that accounts for public sentiment.<sup>13</sup>

## I. BACKGROUND OF NEWBORN GENETIC SCREENING

### A. *PKU Testing and the Rise of Mandatory Genetic Screening for Newborns*

For approximately five decades, state-mandated genetic screening of newborn infants has boomed in the United States.<sup>14</sup> This practice arguably finds its genesis in Dr. Robert Guthrie's scientific breakthrough in the early 1960s, when he developed an inexpensive and sensitive test for detecting the human gene associated with phenylketonuria

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10. *See infra* Part I.

11. *See infra* Part II.

12. *See infra* Part III.

13. *See infra* CONCLUSION.

14. *See* Beth A. Tarini & Aaron J. Goldenberg, *Ethical Issues with Newborn Screening in the Genomics Era*, 13 ANN. REV. GENOMICS & HUM. GENETICS 381, 382 (2012).

(PKU).<sup>15</sup> The procedure for collecting the requisite blood samples for PKU screening is still commonplace and is relatively unchanged since the 1960s—involving a prick of the newborn’s heel<sup>16</sup> and the collection of blood splotches on a screening card.<sup>17</sup> The screening card, which is often referred to as a “Guthrie card,” contains basic demographic data regarding the newborn infant from whom the sample is taken.<sup>18</sup> Such data typically includes information about the infant’s last name, the mother’s name, the infant’s date of birth, and the infant’s height, weight, and gender.<sup>19</sup> PKU testing gained widespread support, due in part to the

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15. See generally Diane B. Paul, *Appendix 5. The History of Newborn Phenylketonuria Screening in the U.S.*, LAW, SCI. & PUB. HEALTH PROGRAM biotech.law.lsu.edu/research/fed/tfgt/appendix5.htm (last visited Sept. 15, 2016). Phenylketonuria is a metabolic disorder, caused by a gene mutation which impairs the body’s ability to produce the enzyme necessary for converting the amino acid phenylalanine into tyrosine. See *id.* Individuals that carry this mutation require a specialized diet in order to allay the onset of developmental retardation, in addition to more immediate symptoms such as seizures, albinism, and unusual body odors. See *id.*

16. Collecting blood samples from the heel of an infant is sometimes referred to as a “heel stick,” and is generally thought to be “a minimally invasive and easily accessible way of obtaining capillary blood samples for various laboratory tests . . . .” Timothy G. Vedder, *Heel Sticks*, MEDSCAPE, <http://emedicine.medscape.com/article/1413486-overview> (last updated Nov. 18, 2015). A heel prick is generally appropriate “whenever capillary blood is an acceptable [sample] source.” *Id.* With improvement in laboratory techniques, which minimize the blood sample size needed for diagnostics, blood specimens that are collected by a heel prick can be used to conduct many other blood tests. *Id.*

17. See Mark A. Hill, *Guthrie Test*, EMBRYOLOGY, [https://embryology.med.unsw.edu.au/embryology/index.php/Guthrie\\_test](https://embryology.med.unsw.edu.au/embryology/index.php/Guthrie_test) (last modified Mar. 16, 2016).

18. See *id.* (providing an image sample of a Guthrie card).

19. See *id.*

availability of preventive treatment,<sup>20</sup> and ultimately became the basis for the first statewide genetic screening program.<sup>21</sup>

The first widespread newborn genetic screening program was launched in Massachusetts, where PKU testing of newborns was imposed by state law.<sup>22</sup> Reportedly, the Massachusetts newborn screening program had two original purposes.<sup>23</sup> As Rachel Schweers notes, first, “the programs created a comprehensive early checkpoint for the American health care system to adequately monitor the health of the infant population via the relatively easy access to a vast majority of newborns.”<sup>24</sup> Second, “the programs were intended to detect metabolic abnormalities known to have severe consequences, including death, that were discoverable by a simple blood test and easily treated during postnatal infancy.”<sup>25</sup>

There was, of course, notable concern regarding the efficacy, value, and safety of widespread PKU testing and treatment.<sup>26</sup> These concerns prompted considerable commentary and even the formation of a task force by the American Academy of Pediatrics, as well as federal funding

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20. “Early diagnosis and treatment [of PKU], consisting merely of a change in the infant’s diet, can successfully prevent all the clinical manifestations of the disease.” Robert Wachbroit, *Making the Grade: Testing for Human Genetic Disorders*, 16 HOFSTRA L. REV. 583, 594 (1988).

21. See Harvey Levy, *Newborn Screening in New England*, MSUD FAM. SUPPORT GRP. (July 20, 2009), <http://www.msud-support.org/index.php/newsletter/29-volume-17-1/163-newborn-screening-in-new-england>.

22. Paul, *supra* note 15.

23. See Rachel L. Schweers, *Newborn Screening Programs: How Do We Best Protect Privacy Rights While Ensuring Optimal Newborn Health?*, 61 DEPAUL L. REV. 869, 875 (2012).

24. *Id.*

25. *Id.*

26. See TWILA BRASE, CITIZEN COUNCIL ON HEALTH CARE, THE UNTOLD PKU TESTING STORY . . . AND WHY IT CHALLENGES GOVERNMENT-MANDATED NEWBORN (GENETIC) SCREENING, 2 (2008), <http://www.cchfreedom.org/pr/CCHCpkunbsReport092408.pdf>.

of research studies, which explored the issues implicated by mass genetic screening.<sup>27</sup> On the other side of the emerging debate, advocacy from entities like the National Association for Retarded Citizens and the Presidential Advisory Commission on Mental Retardation pushed along the movement toward mandating statewide genetic testing.<sup>28</sup>

Two commentators, Ann Andermann and Ingeborg Blancquaert, capture the essence of this debate while opining upon the desirability of newborn genetic screening programs.<sup>29</sup> Andermann and Blancquaert note:

The benefits of genetic screening programs stem from providing high-risk individuals with prevention, early treatment, or reproductive options . . . Critics are concerned that the “geneticization” of health and “routinization” of genetic information are being used to justify the introduction of new technologies before their potential effects are fully understood . . . There is also growing apprehension that economic interests, with additional pressures from consumer groups, might lead to a market-driven approach to genetic screening policy development before the value of screening has been demonstrated . . . In some instances, entire communities have been subjected to discrimination or stigmatization, particularly when there was insufficient community involvement or education when developing screening programs. Therefore . . . there needs to be a more “balanced and informed approach to the development of genetic policies and regulations” through greater consultation, transparency, and public participation.<sup>30</sup>

Yet, as Andermann and Blancquaert further note, “[a]s with any medical intervention, there is a moral imperative for genetic screening to do more good than harm . . . not only from the perspective of individuals and families, but also from that of the target population and of society as a whole.”<sup>31</sup>

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27. See Am. Acad. of Pediatrics, *Newborn Screening: A Blueprint for the Future—A Call for a National Agenda on State Newborn Screening Programs*, 106 PEDIATRICS 389, 389–90 (2000).

28. See *id.*

29. See generally Anne Andermann & Ingeborg Blancquaert, *Genetic Screening: A Primer for Primary Care*, 56 CAN. FAM. PHYSICIAN 333 (2010).

30. *Id.* at 333 (quoting Timothy Caulfield, *Underwhelmed: Hyperbole, Regulatory Policy, and the Genetic Revolution*, 45 MCGILL L.J. 437, 452 (2000)).

31. *Id.* at 337.

Sometimes, however, a tension develops between the interests of individuals and the interests of societies as a whole, and therein lies the conflict at the heart of mandatory genetic screening programs.

### B. *Newborn Genetic Screening Programs in Recent Years*

Ultimately, statewide testing won out the controversy and now every state in the country has a newborn genetics screening program.<sup>32</sup> As of at least 2003, every state requires newborn testing for PKU and congenital hypothyroidism.<sup>33</sup> Alongside this expansion of PKU and hypothyroidism testing, every state now also screens newborn blood samples for additional genetically-linked disorders and illnesses.<sup>34</sup> The exact list of genetically-linked disorders subject to mandatory screening varies widely by state—but most states screen for at least twenty-nine core conditions,<sup>35</sup> with many

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32. See Michelle H. Lewis et al., *State Laws Regarding the Retention and Use of Residual Newborn Screening Blood Samples*, 127 PEDIATRICS 703, 703–04 (2011); see also Kenneth A. Pass, *Lessons Learned from Newborn Screening for Phenylketonuria*, in GENETICS AND PUBLIC HEALTH IN THE 21ST CENTURY 385 (Muin J. Khoury et al. eds., 2000) (discussing the lessons learned from newborn screening for PKU).

33. See U.S. GEN. ACCOUNTING OFFICE, NEWBORN SCREENING: CHARACTERISTICS OF STATE PROGRAMS, GAO-03-449 at 9 (2003); see also Am. Acad. of Pediatrics, *supra* note 27, at 393 (indicating that mandatory PKU testing was performed in all fifty states and the District of Columbia).

34. See Jeffrey J. Stoddard & Philip M. Farrell, *State-to-State Variations in Newborn Screening Policies*, 151 ARCHIVES PEDIATRIC & ADOLESCENT MED. 561, 562 (1997).

35. See STEVE OLSEN & ADAM C. BERGER, CHALLENGES AND OPPORTUNITIES IN USING RESIDUAL NEWBORN SCREENING SAMPLES FOR TRANSLATIONAL RESEARCH: WORKSHOP SUMMARY 1–2 (2010), <http://www.nap.edu/catalog/12981.html>; *National Newborn Screening Status Report*, NAT'L NEWBORN SCREENING & GENETICS RES. CTR. (last updated Nov. 2, 2014), <http://genes-r-us.uthscsa.edu/sites/genes-r-us/files/nbsdisorders.pdf>; see also Am. Coll. of Med. Genetics' Newborn Screening Expert Grp., *Newborn Screening: Toward a Uniform Screening Panel and System*, 8 GENETICS MED. 1S, 13S, 43S (2006) (identifying and recommending twenty-nine core genetically-linked conditions for which newborns should be screened); Beth A. Tarini, *The Current Revolution in Newborn Screening: New Technology, Old Controversies*, 161 ARCHIVES PEDIATRICS & ADOLESCENT MED. 767 (2007); *For Families*, NAT'L NEWBORN



states adding more conditions to the list. Other examples of commonly tested conditions include cystic fibrosis, galactosemia, and sickle cell anemia.<sup>36</sup> Not all conditions included in these panels are treatable or preventable.<sup>37</sup> In fact, this issue in itself has been the subject of a fair degree of controversy, as commentators have argued screening for untreatable conditions is more harmful than helpful.<sup>38</sup>

Some authors suggest that the expansion of newborn screening programs to include untreatable disorders suggests a paradigm shift in the purpose of newborn screening.<sup>39</sup> “Although newborn screening for most disorders still prevents deaths and disability, screening for certain disorders under the new paradigm may carry less dramatic or immediate benefit, as well as benefits beyond those to the newborn.”<sup>40</sup> In part, this paradigm shift was arguably instigated by the federally funded panel, established by the American College of Medical Genetics, which was tasked with establishing criteria for determining the conditions that should be accounted for in newborn screening.<sup>41</sup> The panel recommended broader criteria for evaluating the benefits

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SCREENING & GLOBAL RESOURCE CTR., <http://genes-r-us.uthscsa.edu/parentpage.htm> (last visited Sept. 24, 2016).

36. See *National Newborn Screening Status Report*, *supra* note 35; see generally Piero Rinaldo et al., *Recent Developments and New Applications of Tandem Mass Spectrometry in Newborn Screening*, 16 CURRENT OPINION PEDIATRICS 427 (2004).

37. See generally Anne Marie Catharina Plass et al., *Neonatal Screening for Treatable and Untreatable Disorders: Prospective Parents' Opinions*, 125 PEDIATRICS e99 (2010) (describing a similar concern in the expansion of newborn screening programs in the Netherlands).

38. *But see* Donald B. Bailey, Jr. et al., *Newborn Screening for Developmental Disabilities: Reframing Presumptive Benefit*, 95 AM. J. PUB. HEALTH 1889, 1889 (2005) (advocating for a broader perspective of “benefit” that would justify screening for untreatable conditions).

39. Scott D. Grosse et al., *From Public Health Emergency to Public Health Service: The Implications of Evolving Criteria for Newborn Screening Panels*, 117 PEDIATRICS 923, 923 (2006).

40. *Id.*

41. See *id.* at 924.

associated with newborn screening.<sup>42</sup> The new criteria “include all ‘outcomes’ and ‘negative consequences’ that can be optimized or prevented . . . [as well as] benefits to families from timely knowledge of recurrence risks and the avoidance of ‘diagnostic odysseys’ associated with delayed diagnoses . . . .”<sup>43</sup>

Under the new paradigm, newborn screening is not conducted solely for the benefit of infants. Rather, it extends to the families of infants and society at large. As March of Dimes President, Dr. Jennifer L. Howse, notes, in commenting on Newborn Screening Saves Lives Reauthorization Act, “[g]iven that one in every 300 infants has a condition that can be detected through this screening, newborn screening represents an indispensable investment in health, families, and our economy.”<sup>44</sup> Any state-mandated activity is going to tax the privacy interests of individual persons. But with some doubt as to the justifications for newborn screening programs to begin with, there arise some very serious concerns regarding the attenuated justifications for allowing states to utilize potentially ill-gotten gains in a way that would further cast doubt on the practice as a whole.

### C. *Residual Dried Blood Samples and Non-Screening Uses*

All states mandate newborn testing,<sup>45</sup> with relatively little or sometimes no disclosure regarding the state’s retention of residual dried blood samples, the bio-banking of those samples, or the use of such samples in unrelated

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42. *See id.*

43. *Id.* at 924–25.

44. *Newborn Screening Saves Lives Reauthorization Act Goes to President for Signature into Law*, PRNEWswire (Dec. 10, 2014, 5:53 PM), <http://www.prnewswire.com/news-releases/newborn-screening-saves-lives-reauthorization-act-goes-to-president-for-signature-into-law-300008138.html>.

45. U.S. GEN. ACCOUNTING OFFICE, *supra* note 33. However, thirty-three states provide exemptions from newborn testing for religious reasons, and thirteen additional states provide exemptions from testing for any reason. *Id.*

research studies.<sup>46</sup> Typically, residual dried blood samples from Guthrie cards are stored anywhere from two weeks to an indefinite period of time, depending on state law.<sup>47</sup> Olney et al. surveyed state use of newborn blood spots, to which forty-nine states responded, and found that seventy-four percent of the respondents used residual samples to evaluate the screening tests themselves, fifty-two percent of the respondents used residual samples for clinical or forensic testing, and twenty-eight percent of the respondents used residual samples in epidemiologic studies.<sup>48</sup>

Some authors have suggested that there is an emerging trend toward “biobanking” in the United States.<sup>49</sup> As of 2008, for instance, researchers in the United States had banked an estimated 270 million samples, which was growing at the rate of about 20 million new samples per year.<sup>50</sup> This trend has been fueled in part by relatively recent advancements in human genome mapping and the consistently decreasing costs of genetic testing.<sup>51</sup> “The first time scientists sequenced a person’s entire genome, it took more than a decade and cost hundreds of millions of dollars. [As of August of 2014], such sequencing takes less than twenty-four hours and costs less

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46. See Richard S. Olney et al., *Storage and Use of Residual Dried Blood Spots from State Newborn Screening Programs*, 148 J. PEDIATRICS 618, 619–21 (2006).

47. See Linda Kharaboyan et al., *Storing Newborn Blood Spots: Modern Controversies*, 32 J.L. MED. & ETHICS 741, 743 (2004).

48. Olney et al., *supra* note 46, at 619–20.

49. See Jean E. McEwen & Philip R. Reilly, *Stored Guthrie Cards as DNA “Banks,”* 55 AM. J. HUM. GENETICS 196, 196 (1994). A “biobank” is a repository of biological materials, such as those storing tissue samples for later use in medical and biotechnological research. See VIRTUAL OFFICE OF GENOMICS, POPULATION-BASED BIOBANKS AND GENETICS RESEARCH IN CONNECTICUT (2007), <http://www.ct.gov/dph/LIB/dph/Genomics/biobankspolicybrief.pdf>.

50. Susanne B. Haga & Laura M. Beskow, *Ethical, Legal, and Social Implications of Biobanks for Genetic Research*, 60 ADVANCES GENETICS 505, 507 (2008).

51. See Peter Ubel, *Will Lowering the Price of Genetic Testing Raise the Cost of Medical Care?*, FORBES (Aug. 25, 2014, 2:51 PM), <http://www.forbes.com/sites/peterubel/2014/08/25/will-lowering-the-price-of-genetic-testing-raise-the-cost-of-medical-care/#26173a253f0f>.

than \$5000 . . . .”<sup>52</sup> With the cost of human genome mapping on the decline, the notion of mass biobanking becomes more feasible, at least insofar as it is an economic matter.

This trend toward biobanking would invariably be encouraged and supported by favorable informed consent policies applied to state-mandated genetic screening programs. For example, the State of Michigan has founded the Michigan BioTrust for Health, which indefinitely stores residual dried blood samples taken from the State’s newborn screening program unless the guardian of a newborn (or the newborn upon reaching the age of majority) opts out of the process.<sup>53</sup> The BioTrust for Health website provides a snapshot description of the evolution of the dried blood spot storage policy of the State of Michigan:

Blood spots have always been stored [in the State of Michigan] for some period of time following newborn screening, but the length of time has changed over the years. In the 1970s, samples were saved for 7 years. In the 1980s, the Department of Health and Human Services (DHHS) changed the policy to store each sample for 21.5 years following the receipt of legal advice. In 2008, the policy was revised for indefinite storage of blood spots to align with a recommendation from the Governor’s Commission on Genetic Privacy and Progress. Today, blood spots are still stored indefinitely (forever) once newborn screening is completed. The changes in storage policy have allowed for a collection of stored blood spots dating back to July 1984. Any samples received by the

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52. *Id.*

53. *Michigan BioTrust for Health*, MICH. DEP’T HEALTH & HUM. SERVS., [http://www.michigan.gov/mdhhs/0,5885,7-339-73971\\_4911\\_4916\\_53246---,00.html](http://www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916_53246---,00.html) (last visited Apr. 25, 2016). See generally *BioTrust Frequently Asked Questions*, MICH. DEP’T HEALTH & HUM. SERVS., [http://www.michigan.gov/documents/mdch/FAQ\\_Part\\_2\\_What\\_Is\\_The\\_Michigan\\_BioTrust\\_for\\_Health\\_490152\\_7.pdf](http://www.michigan.gov/documents/mdch/FAQ_Part_2_What_Is_The_Michigan_BioTrust_for_Health_490152_7.pdf) (last visited Apr. 25, 2016) (“MDHHS is responsible for the blood spot samples, holding them ‘in trust’ for future research. The Michigan Neonatal Biobank ([www.mnbb.org](http://www.mnbb.org)), a 501c3 non-profit charitable organization, is responsible for storage and day-to-day management of the blood spots.”).

state laboratory on infants born before July 1984 have been destroyed.<sup>54</sup>

Interestingly, the Policy and Procedure Manual of the Michigan Department of Community Health explicitly states that the dried blood samples remain the “qualified” property of the Michigan Department of Community Health while such samples remain in storage.<sup>55</sup>

The beneficial applications of biobanking are enticing. Some sources report that “epigenetic information stored on archived Guthrie cards provides a retrospective view of the epigenome at birth, a powerful new application for the card that could help understand disease and predict future health.”<sup>56</sup> Other authors have noted that biobanks allow researchers to develop “target-orientated preventive, diagnostic and therapeutic interventions” in order to “promote personalized medicine and health care.”<sup>57</sup> Epidemiological studies, based on surveillance, are made possible by gathering data from population-based biobanks and analyzing genetic information in the context of donor demographics.<sup>58</sup>

It is unsurprising then that the Centers for Disease Control has indicated in the last few years that it intends to coordinate a biobank of samples taken from state newborn

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54. *Michigan BioTrust for Health—Consent Options*, MICH. DEP’T HEALTH & HUM. SERVS., [http://www.michigan.gov/mdhhs/0,5885,7-339-73971\\_4911\\_4916\\_53246-244016--,00.html](http://www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916_53246-244016--,00.html) (last visited Apr. 25, 2016).

55. *Policy and Procedure Manual*, MICH. DEP’T CMTY. HEALTH, [http://www.michigan.gov/documents/mdch/11.1\\_NBSspecimenretentionpolicy\\_316310\\_7.pdf](http://www.michigan.gov/documents/mdch/11.1_NBSspecimenretentionpolicy_316310_7.pdf) (last visited Apr. 25, 2016).

56. *Archived Guthrie Cards Find a New Purpose*, SCIENCE DAILY (Aug. 22, 2012), <http://www.sciencedaily.com/releases/2012/08/120822181346.htm>; see also Huriya Beyan et al., *Guthrie Card Methylomics Identifies Temporally Stable Epialleles That Are Present at Birth in Humans*, 22 GENOME RES. 2138, 2138 (2012).

57. Angela Brand et al., *Biobanking for Public Health*, in TRUST IN BIOBANKING: DEALING WITH ETHICAL, LEGAL AND SOCIAL ISSUES IN AN EMERGING FIELD OF BIOTECHNOLOGY 3, 7 (Peter Dabrock et al. eds., 2012).

58. See generally *id.* at 9–11.

screening programs.<sup>59</sup> In doing so, the Centers for Disease Control hopes to generate materials for epidemiology research.<sup>60</sup> The exact number of states that biobank newborn blood samples is unknown, as a majority of states have no written policy regarding the length of retention of such samples.<sup>61</sup> However, the potential for generating a single, national cache of samples from state programs is well recognized and ultimately highlights the pertinence of this discussion.<sup>62</sup> Whatever controversies may arise, newborn screening programs appear to be deeply anchored in state practices and are likely here to stay.

## II. LITIGATION INVOLVING RESIDUAL SAMPLES FROM NEWBORN SCREENING

Mandatory newborn screening has already seen a fair degree of litigation. One noteworthy case, *Douglas County v. Anaya*, provides valuable insight into the constitutionality of mandatory screening.<sup>63</sup> Several other high profile cases have explored issues regarding the use of residual samples for

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59. See *Public Health Genomics Program Review*, CTRS. DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/genomics/about/reports/2008/chap5.htm> [<https://web.archive.org/web/20150908071645/http://www.cdc.gov/genomics/about/reports/2008/chap5.htm>] (last visited Oct. 21, 2013).

60. See *id.*

61. See Bradford L. Therrell et al., *Status of Newborn Screening Programs in the United States*, 117 PEDIATRICS S212, S222 (2006) (indicating that most states have no written policy on the length of retention of Guthrie card samples).

62. Large scale genetic biobanks are controversial, with some commentators expressing concern over the need for revisiting traditional and commonly accepted methods of obtaining informed consent in the context of biobanking. See generally Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343 (2007); Oonagh Corrigan, *Biobanks: Can They Overcome Controversy and Deliver on Their Promise to Unravel the Origins of Common Diseases?*, 40 MED. EDUC. 500 (2006). As Greely comments, procedures which obtain broad and general consent should be replaced with consent mechanisms that give subjects greater control over potentially objectionable uses of their information and biological samples. Greely, *supra*, at 343.

63. See generally *Douglas Cty. v. Anaya*, 694 N.W.2d 601 (Neb. 2005).

purposes other than newborn screening, such as program development and third-party research.<sup>64</sup> These cases are instructive in that they illustrate some of the major legal issues implicated by mandatory newborn screening programs and serve as a starting point for analyzing the best approach to dealing with the problem of consent. This Part discusses the constitutionality of mandatory genetic newborn screening before exploring the interplay of genetic privacy and newborn screening and the legality of sharing residual blood samples with third parties.<sup>65</sup>

A. *The Constitutionality of Mandatory Genetic Newborn Screening*

*Anaya*, which was heard by the Nebraska Supreme Court, entertained federal constitutional challenges to Nebraska's newborn genetic screening program.<sup>66</sup> In 2003, Rosa Anaya was born into the Anaya family during a homebirth and in the absence of a licensed physician.<sup>67</sup> At the time of Rosa Anaya's birth, a Nebraska statute provided that "[a]ll infants born in the State of Nebraska shall be screened for phenylketonuria, primary hypothyroidism, biotinidase deficiency, galactosemia, hemoglobinopathies . . . (MCAD) deficiency, and such other metabolic diseases . . ."<sup>68</sup> The month following Rosa Anaya's birth, the Nebraska Department of Human Health Services (NDHHS) reviewed the records of the birth and noted that Rosa Anaya had not

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64. See, e.g., *Higgins v. Tex. Dep't of Health Servs.*, 801 F. Supp. 2d 541, 544 (W.D. Tex. 2011); *Bearder v. State*, 806 N.W.2d 766, 769 (Minn. 2011); First Amended Complaint, *supra* note 7.

65. See *infra* Part II.A–C.

66. See *Anaya*, 694 N.W.2d at 603–04. A similar challenge was raised in federal district court in the District of Nebraska. See *Spiering v. Heineman*, 448 F. Supp. 2d 1129, 1131 (D. Neb. 2006).

67. *Anaya*, 964 N.W.2d at 604.

68. NEB. REV. STAT. § 71-519 (2003).

undergone the screening process required by state's newborn screening statute.<sup>69</sup>

The NDHHS delivered a brochure to the Anaya family detailing the requirements of the screening program, as well as the method of collection, together with a request to have Rosa Anaya screened.<sup>70</sup> The Anaya family refused to submit the child for blood spot collection, claiming that the activity was contrary to their "sincerely held religious beliefs" that blood-letting would reduce their infant's lifespan.<sup>71</sup> The NDHHS initiated legal proceedings against the Anaya family, and the trial court ultimately found in favor of the government.<sup>72</sup> The Anaya family appealed the matter, claiming that the statute violated their First Amendment right to free exercise of religion.<sup>73</sup> The Anaya family also argued that the statute violated their substantive due process rights as parents under the Fourteenth Amendment.<sup>74</sup>

The Nebraska Supreme Court rejected the Anayas' First Amendment claim, finding that the statute was neutral and generally applicable.<sup>75</sup> As such, the matter did not require strict scrutiny, and Nebraska was not required to demonstrate a compelling state interest.<sup>76</sup> Rather, the First Amendment claim was subject to review under a "rational basis test,"<sup>77</sup> which is the lowest constitutional standard of review and which gives the most deference to the government. Under this framework, the *Anaya* court found

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69. *Anaya*, 694 N.W.2d at 604.

70. *See id.*

71. *Id.*

72. *See id.*

73. *Id.*

74. *Id.* at 604–05.

75. *Id.* at 606–08.

76. *Id.*

77. *Id.* at 608.



that Nebraska's screening program was rationally related to the state's legitimate interest in safeguarding public health and, thus, did not violate the First Amendment.<sup>78</sup>

The court reached a similar conclusion with respect to the Anayas' Fourteenth Amendment claim, which the court concluded was also subject to the rational basis test.<sup>79</sup> In analyzing the Anayas' parental due process claim, the court noted that mandatory screening could be likened to mandatory immunization and that mandatory immunization has been found to constitute a permissible use of state police power.<sup>80</sup> The *Anaya* court also noted that "[s]ociety's interest in protecting against the spread of disease takes precedence over parental rights . . . ."<sup>81</sup> The *Anaya* court quoted the U.S. Supreme Court for the proposition that "the power of the parent, even when linked to a free exercise claim, may be subject to limitation . . . if it appears that parental decisions will jeopardize the health or safety of the child, or have a potential for significant social burdens."<sup>82</sup> The Anaya family appealed to the U.S. Supreme Court, but the Court declined to hear the matter.<sup>83</sup>

As the *Anaya* case illustrates, the state-mandated collection of blood samples from newborn infants, for the purpose of genetic screening, will likely survive constitutional attacks if it is neutral and generally

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78. *Id.*

79. *Id.* at 607–08.

80. *See id.* at 607 (citing *Boone v. Boozman*, 217 F. Supp. 2d 938, 954 (E.D. Ark. 2002)).

81. *Id.* at 607 (citing *Boone*, 217 F. Supp. 2d at 954).

82. *Id.* (quoting *Wisconsin v. Yoder*, 406 U.S. 205, 233–34 (1972)).

83. *See Order Denying Certiorari, Anaya v. Douglas Cty.*, 546 U.S. 826 (2005) (No. 04-1718). It is worthwhile to note that the federal court in the District of Nebraska reached conclusions similar to those found in *Anaya*, namely that strict scrutiny does not apply to state-mandated newborn screening and the right of parents to rear their children does not trump the state's power to advance public health and safety. *See Spiering v. Heineman*, 448 F. Supp. 2d, 1129, 1138–42 (D. Neb. 2006).

applicable, and if it is done for the general welfare of the citizens of a state.<sup>84</sup> Understanding the contours of the constitutionality of newborn screening is important because the activity that has garnered the most controversy is not the mere collection and testing of such samples, but rather what states do with those samples beyond basic screening.<sup>85</sup> Unlike the basic screening at issue in *Anaya*, the retention of and experimentation with such samples has no connection to the well-being of the specific child and therefore is markedly unlike immunization.<sup>86</sup> On the other hand, there might still be a rational relationship between these additional activities and the health and welfare of the citizens of the state at large.<sup>87</sup> Ultimately the question of constitutionality, with respect to the retention and use of such samples, remains open.

#### B. *The Interplay of Genetic Privacy and Newborn Screening Statutes*

Another case, *Bearder v. State*, provides a snapshot of the interplay between genetic privacy and newborn screening statutes.<sup>88</sup> In *Bearder*, the families of twenty-five children, who had been tested under Minnesota's newborn screening program, filed suit against the State of Minnesota, the Minnesota Department of Health, and the Minnesota Commissioner of Health.<sup>89</sup> The *Bearder* plaintiffs complained that the defendants had violated the Minnesota "Genetic Privacy Act" by allowing the state's newborn screening program to utilize residual dried blood samples in non-screening activities and by disseminating blood samples to a

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84. See, e.g., *Anaya*, 694 N.W.2d at 603–08.

85. See *infra*, Part II.B–C.

86. See *Anaya*, 694 N.W.2d at 604.

87. See generally *id.*

88. See *Bearder v. State*, 806 N.W.2d 766 (Minn. 2011).

89. *Id.* at 769.

third-party research facility.<sup>90</sup> The plaintiffs, in an amended complaint, subsequently raised various tort and constitutional causes of action in addition to the alleged statutory violation.<sup>91</sup>

As the Minnesota Supreme Court noted, the state's genetic screening program typically expended seventy percent of each newborn's dried blood sample.<sup>92</sup> The residue of each sample, if any, was stored indefinitely by the state unless an appropriate party specifically requested the destruction of the specimen.<sup>93</sup> As of at least the date of publication of the *Bearder* opinion, more than 50,000 blood samples had been used in studies for purposes unrelated to initial newborn screening.<sup>94</sup> In researching some of these unrelated studies, Vani Kilakkathi found "one Minnesota study that had used residual bloodspot samples to study mercury exposure levels in the Lake Superior Basin . . . ."<sup>95</sup> Kilakkathi also found "several articles from the 1990s that used residual samples to examine the prevalence of HIV in newborns to formulate recommendations about screening pregnant women for HIV."<sup>96</sup>

Additionally, Mayo Medical Laboratories (Mayo), the third-party service provider for Minnesota newborn screening program, conducted at least some of the studies using newborn blood spots from Minnesota.<sup>97</sup> Mayo's studies

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90. *See id.*

91. *Id.*

92. *Id.* at 770.

93. *Id.*

94. *See id.* at 771.

95. VANI KILAKKATHI, COUNCIL FOR RESPONSIBLE GENETICS, NEWBORN SCREENING IN AMERICA: PROBLEMS AND POLICIES 11 (2012), <http://www.councilforresponsiblegenetics.org/pageDocuments/WNMAKEPP1P.pdf>. Kilakkathi's report offers an excellent survey of state policies regarding state retention of newborn blood spots and the consent procedures adopted in each state. *See id.* at 29–37.

96. *Id.* at 11.

97. *See Bearder*, 806 N.W.2d at 771.

were conducted pursuant to its contractual arrangement with Minnesota, which permitted Mayo to use the residue of the blood samples so long as they were “de-identified” or written consent was given.<sup>98</sup> The practices of the State of Minnesota have vastly changed, as Minnesota now uses opt-in procedures for samples collected after August 1, 2014.<sup>99</sup>

Ultimately in *Bearder*, the trial court dismissed all of the plaintiffs’ claims on summary judgment, finding that the tort and constitutional claims failed to state a cause of action and the statutory claims failed as a matter of law.<sup>100</sup> The trial court found that no statutory violation had occurred because the samples did not constitute “genetic information” within the meaning of Minnesota’s Genetic Privacy Act.<sup>101</sup> The trial court noted that the statutory claims also failed because Minnesota’s Genetic Privacy Act did not supersede the State’s newborn screening laws.<sup>102</sup> The Minnesota Court of Appeals affirmed the trial court, holding that the Minnesota Genetic Privacy Act did not curtail the broad power of the Minnesota Department of Health, but noting that the blood samples were “genetic information” within the meaning of the Act.<sup>103</sup>

Since 2006, Minnesota’s Genetic Privacy Act has provided that genetic information may only be collected, used, stored, and disseminated pursuant to written informed consent.<sup>104</sup> The statute, however, does not apply to uses

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98. *See id.*

99. *See Newborn Screening Information for Families: Parental Options*, MINN. DEP’T OF HEALTH, <http://www.health.state.mn.us/divs/phl/newborn/families/parentaloptions.html#Example1> (last visited Apr. 26, 2016) [hereinafter *Newborn Screening Information for Families*].

100. *See Bearder*, 806 N.W.2d at 769.

101. *Id.*

102. *Id.*

103. *See Bearder v. State*, 788 N.W.2d 144, 149–50 (Minn. Ct. App. 2010).

104. *See* MINN. STAT. § 13.386 (2015).

“otherwise expressly provided by law . . . .”<sup>105</sup> The Minnesota Supreme Court reviewed and reversed the lower courts, finding that the blood samples were inextricably linked to the genetic information contained with each sample, that the Genetic Privacy Act applied to the actions of the Department of Health, and that the State’s use of the blood samples was limited to those uses authorized by statute; namely testing, recording and reporting results, maintaining a registry for follow-up care, and otherwise complying with federal laws.<sup>106</sup> With respect to any samples collected prior to August 1, 2014, the Minnesota Department of Health indicates that they will be or have been destroyed pursuant to a retention policy that it appears to have adopted in 2014.<sup>107</sup>

The precise lesson to be gleaned from *Bearder* is that even if a state has the power to share residual samples with third-parties, without first obtaining informed consent, the state’s legislature could curtail such conduct by enacting legislation under its police powers on the theory that individuals have a privacy interest in their genetic code. More broadly, however, the situation in Minnesota exposes two of the major concerns raised by mandatory screening, which are whether the general public can trust states to handle residual blood samples in a discreet manner and whether the de-identification of residual samples is adequate

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105. *Id.*

106. *See Bearder*, 806 N.W.2d at 774, 776–77.

107. *See Newborn Screening Information for Families*, *supra* note 99. Minnesota Statute § 144.125 now sets forth guidelines on the how the State’s newborn blood screening program may be stored and how residual dried blood spots may be used. MINN. STAT. § 144.125 (2015). It also sets forth some guidelines on when the State must obtain informed consent to conduct unrelated research studies, and uses the “opt-in” method of consent. *See id.* The Statute provides that “[w]ith the written, informed consent of a parent or legal guardian, the Department of Health may use blood samples and test results for public health studies or research not related to newborn screening, and upon approval by the Department . . . share samples and test results with external parties for public health studies or research.” *Id.* It appears that while the battle for informed consent may have fallen short in the judiciary of Minnesota, it was won in the legislature.

to protect the privacy interests of the donor infants. Public confidence in government acts is important and must be taken into account when crafting any widespread policy that deals with a controversy of this magnitude.<sup>108</sup>

C. *The Illegality of Sharing Residual Dried Blood Samples with Third-Parties*

As the State of Texas has shown, it is tempting to make use of resources that are otherwise seen as a waste. Texas was handling residual dried blood samples in a manner similar to the State of Minnesota, albeit in a manner that was arguably more egregious than mere third-party sharing.<sup>109</sup> Since at least 1991, the Texas Department of State Health Services (TDSHS) has mandated the collection of blood spots from newborns.<sup>110</sup> Unlike Minnesota, however, Texas has utilized an “opt-out” system for newborn screening—the state presumed consent to newborn screening unless the parents of a particular child declined to allow the procedure.<sup>111</sup>

With respect to the residue of the newborn blood spots, Texas has “often provided blood samples to other states . . . [as well as] distributed newborn bloodspots for research projects ranging from various University-sponsored disease studies, to the creation of a Department of Defense-sponsored international database . . . and to for-profit companies’ development of more effective screening test-

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108. The issue of public confidence in state action is further discussed below. See *infra* Part III.B.

109. See generally *Higgins v. Tex. Dep’t of Health Servs.*, 801 F. Supp. 2d 541 (W.D. Tex. 2011); First Amended Complaint, *Beleno v. Tex. Dep’t of State Health Servs.*, No. SA-09-CA-0188-FB, 2009 WL 5072239 (W.D. Tex. Sept. 29, 2009).

110. See *Higgins*, 801 F. Supp. 2d at 550; First Amended Complaint, *Beleno*, 2009 WL 5072239.

111. See TEX. HEALTH & SAFETY CODE ANN. § 33.012 (West 2010).

kits.”<sup>112</sup> Reports also indicate that Texas allegedly exchanged blood samples for monetary and non-monetary remuneration, such as for the payment of fees or the provision of laboratory supplies.<sup>113</sup> Thus, Texas’ actions take this issue to a new level, raising concerns about the propriety of sharing residual blood samples for financial gain.

The activities of the TDSHS resulted in two media-hyped lawsuits which garnered national attention. The earlier of these cases, *Beleno v. Texas Department of Health Services*, was a class action matter alleging that the use of the samples in unrelated research and third-party sample sharing violated the Fourth and Fourteenth Amendments.<sup>114</sup> The *Beleno* plaintiffs filed suit against several parties, the most pertinent of which was the TDSHS and its Commissioner.<sup>115</sup>

In litigating the matter, the defendants argued that the plaintiffs had failed to state a cause of action because there could be no unlawful seizure where the samples were lawfully taken pursuant to Texas newborn screening

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112. See Sandra J. Carnahan, *Biobanking Newborn Bloodspots for Genetic Research Without Consent*, 14 J. HEALTH CARE L. & POL’Y 299, 305–06 (2011) (citing Mary Ann Roser, *State Agency Swaps Babies’ Blood for Supplies*, AUSTIN AM.-STATESMAN (May 10, 2010), <http://www.statesman.com/news/texas-politics/state-agency-swaps-babies-blood-for-supplies-0678302.html>; *Newborn Screening: Use of NBS Blood Spots After Completion of Newborn Screening*, TEX. DEPT’ ST. HEALTH SERVS., <http://www.dshs.state.tx.us/lab/nbsBloodspotsUse.shtm> (last updated Jan. 23, 2015).

113. See Becca Aaronson, *Lawsuit Alleges DSHS Sold Baby DNA Samples*, TEX. TRIB. (Dec. 8, 2010), <https://www.texastribune.org/2010/12/08/lawsuit-alleges-dshs-sold-baby-dna-samples>; Jason Douglass, *Texas Sells Babies’ Blood, Second Lawsuit Filed*, INFOWARS (Dec. 10, 2010), <http://www.infowars.com/texas-sells-babies-blood-second-lawsuit-filed>.

114. First Amended Complaint, *Beleno*, 2009 WL 5072239.

115. See Defendants’ Motion to Dismiss or for Summary Judgment Based on Mootness, *Beleno v. Tex. Dep’t of State Health Servs.*, No. SA-09-CA-0188-FB, 2009 WL 5072237, at 1 n.1 (W.D. Tex. July 2, 2009). The other defendants in the *Beleno* matter included Nancy W. Dickey (Vice Chancellor for Health Affairs of the Texas A&M University System and President of the Texas A&M University System Health Science Center), Roderick E. McCallum (Interim Dean of the School of Rural Public Health), and Texas A&M University. *Id.*

statutes.<sup>116</sup> The *Beleno* defendants also argued that there could be no violation of plaintiffs' liberty interest in privacy where the state had already complied with applicable state and federal regulations regarding the maintenance of medical information.<sup>117</sup> In the alternative, the *Beleno* defendants argued that the screening laboratory was HIPAA compliant, HIPAA already codified the privacy interest implicated by the claims, and any de-identified specimens were not subject to the same privacy protections as identified specimens.<sup>118</sup>

Midway through the course of the *Beleno* litigation, Texas passed an amendment to its screening laws requiring the TDSHS to create and utilize a disclosure form explaining to the parents of newborns that residual samples may be retained by the department or laboratory, the manner in which the samples are managed and used, and that the parents may limit the use of children's genetic materials to screening with a written request.<sup>119</sup> The *Beleno* matter was ultimately resolved on a settlement, which among other things, involved requiring the TDSHS to publish and disclose the research for which residual samples had been used.<sup>120</sup> Notably, the settlement agreement required the State of Texas to destroy an estimated five million residual blood samples!<sup>121</sup> It was reported, however, that pursuant to the settlement agreement, "the 10–12 000 [sic] blood spots

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116. See Defendants' Motion to Dismiss Plaintiffs' Original Complaint, *Beleno v. Tex. Dep't of State Health Servs.*, No. SA-09-CA-0188-FB, 2009 WL 5072234 (W.D. Tex. May 29, 2009).

117. See *id.*

118. See *id.* "HIPAA" is acronym that stands for the Health Insurance Portability and Accountability Act of 1996. *Id.*

119. TEX. HEALTH & SAFETY CODE ANN. § 33.0111 (West 2010).

120. *Higgins v. Tex. Dep't of Health Servs.*, 801 F. Supp. 2d 541, 545–46 (W.D. Tex. 2011).

121. See Monica J. Allen et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY 1675, 1680 (2010).



already released to some 35 research projects could continue to be used."<sup>122</sup>

The second lawsuit brought in Texas, *Higgins v. Texas Department of Health Services*, involved the parents of two children seeking declaratory and injunctive relief in federal court.<sup>123</sup> As the *Higgins* court summarized, the plaintiffs sought an order commanding state officials to "account for and destroy all blood samples and spots . . . which Defendants have distributed, sold, bartered, or traded without informed parental consent . . . to advise Plaintiffs for what purposes Defendants used the blood samples and spots of Plaintiffs' children and [to] disclose all financial transactions involved . . . ."<sup>124</sup> The West Texas District Court dismissed the complaint for lack of standing and mootness.<sup>125</sup>

Among other things, the West Texas District Court noted that the *Higgins* plaintiffs had not articulated a harm different from the harm resolved in *Beleno*.<sup>126</sup> The *Higgins* court also noted that there was no ongoing harm, as Texas had already passed an amendment addressing the issue of non-consensual use of residual samples.<sup>127</sup> Due to the settlement of the *Beleno* controversy, the legality of the State of Texas' conduct remains untested. Whether fundamental liberty, as embodied in the Fourteenth Amendment, requires informed consent for the use of residual dried blood samples in research aimed at improving the screening process, remains unanswered. Outstanding still are the issues of what would even constitute confidential, genetic information, and, assuming such information is lawfully obtained, whether such information may be bartered to third-parties for use in wholly unrelated research. *Beleno* demonstrates the potential for the abuse of a newborn

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122. *Id.*

123. *Higgins*, 801 F. Supp. 2d at 546.

124. *Id.* at 551.

125. *See id.* at 551-55.

126. *See id.* at 552.

127. *See id.*

screening program by state actors and brings to light issues of widespread concern.

### III. THE ISSUE OF INFORMED CONSENT & POTENTIAL ENFORCEMENT MECHANISMS

While it is tempting, in discussing the establishment of uniform national standards, to look for a federal solution, one is not always forthcoming. Even if it is forthcoming, the solution is not always satisfying. This Part is separated into three subparts.<sup>128</sup> The first subpart explores potential mechanisms for implementing uniform standards.<sup>129</sup> The second subpart considers how to balance the value of genetic testing with social interests in the context of informed consent.<sup>130</sup> The third subpart explores previous suggestions for dealing with the issue of informed consent, while setting forth the author's recommended approach.<sup>131</sup>

#### A. *Mechanisms for Implementing a Uniform Standard*

There have been calls to action for unifying state policies regarding mandatory screening and the handling of residual dried blood samples—but very little uniformity has emerged. One reason for this lack of uniformity is the struggle to find an appropriate widespread enforcement mechanism for compelling states and/or laboratories to adopt more complex informed consent policies. As the *Bearder* case demonstrates, simply granting every U.S. citizen a statutory right to privacy for their genetic information (or perhaps even a property interest) would cleanly solve the problem by

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128. *See infra* Part III.

129. *See infra* Part III.A.

130. *See infra* Part III.B.

131. *See infra* Part III.C.

prohibiting sample sharing with third-parties absent consent.<sup>132</sup>

Such a solution is sweeping, but not unimaginable. After all, the federal government did pass the Genetic Information Nondiscrimination Act of 2008 (GINA), which established limitations on the disclosure of genetic information in the insurance and employment contexts.<sup>133</sup> Yet, GINA was an exercise of the federal government's power under the Commerce Clause, limited to employment and insurance providers—two areas that have a close nexus to interstate commerce.<sup>134</sup> The same rationale would be a tough sell in the context of the purely intrastate handling of residual dried blood samples. Furthermore, the power of state sovereigns to regulate public health and safety runs deep in our country's traditions.<sup>135</sup>

At least two authors have considered the Common Rule and argued for its application to the retention and use of residual newborn blood samples.<sup>136</sup> The Common Rule refers to the Federal Policy for the Protection of Human Subjects, which was published in 1991.<sup>137</sup> The Common Rule was

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132. See *supra* Part II.B.

133. See Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008). See generally *Questions and Answers for Small Businesses: EEOC Final Rule on Title II of the Genetic Information Nondiscrimination Act of 2008*, U.S. EQUAL EMP'T OPPORTUNITY COMM'N, [http://www.eeoc.gov/laws/regulations/gina\\_qanda\\_smallbus.cfm](http://www.eeoc.gov/laws/regulations/gina_qanda_smallbus.cfm) (last visited Nov. 2, 2013).

134. See Genetic Information Nondiscrimination Act, 122 Stat. 881.

135. See Jorge E. Galva et al., *Public Health Strategy and the Police Powers of the State*, 120 PUB. HEALTH REP. 20, 20 (2005) ("The doctrine of state 'police power' was adopted in early colonial America from firmly established English common law principles mandating the limitation of private rights when needed for the preservation of the common good.").

136. See Carnahan, *supra* note 112, at 315-25; Katherine Drabiak-Syed, *Legal Regulation of Banking Newborn Blood Spots for Research: How Bearder and Beleno Resolved the Question of Consent*, 11 HOUS. J. HEALTH L. & POL'Y 1 (2011).

137. FEDERAL POLICY FOR HUMAN SUBJECTS ('COMMON RULE'), U.S. DEP'T OF HEALTH & HUM. SERVS., <http://www.hhs.gov/ohrp> (last visited Oct. 20, 2013).

codified in the regulations of fifteen different federal agencies<sup>138</sup> and, in three other agencies, adopted by executive order or statute.<sup>139</sup> The Common Rule, for each applicable agency, sets forth guidelines for the maintenance of institutional review boards, standards of obtaining informed consent from human subjects, and assurances of compliance.<sup>140</sup>

However, the Common Rule does not apply to the states in any direct, binding manner and is limited to research that is funded or undertaken by the applicable federal agencies.<sup>141</sup> Additionally, de-identified samples would not be subject to human research protection under the guidelines of the Common Rule.<sup>142</sup> Ultimately, grounding a solution to the

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(select “Regulation and Policy,” then select “Regulations,” then select “Common Rule”).

138. See 7 C.F.R. §§ 1c.101–1c.124. (Department of Agriculture); 10 C.F.R. §§ 745.101–745.124 (Department of Energy); 14 C.F.R. §§ 1230.101–1230.103 (National Aeronautics and Space Administration); 15 C.F.R. §§ 27.101–27.124 (Department of Commerce, National Institute of Standards and Technology); 16 C.F.R. §§ 1028.101–1028.124 (Consumer Product Safety Commission); 22 C.F.R. §§ 225.101–225.124 (Agency for International Development); 24 C.F.R. § 60.101 (Department of Housing and Urban Development); 28 C.F.R. §§ 46.101–46.124 (Department of Justice, National Institute of Justice); 32 C.F.R. §§ 219.101–219.124 (Department of Defense); 34 C.F.R. §§ 97.101–97.124 (Department of Education); 38 C.F.R. §§ 16.101–16.124 (Department of Veteran Affairs, Office of Research Oversight and Office of Research and Development); 40 C.F.R. §§ 26.101–26.124 (Environmental Protection Agency, Research and Development); 45 C.F.R. §§ 46.101–46.409 (Department of Health and Human Services); 45 C.F.R. §§ 690.101–690.124 (National Science Foundation); 49 C.F.R. §§ 11.101–11.124 (Department of Transportation).

139. See 45 C.F.R. §§ 46.101–46.409 (applicable to Central Intelligence Agency by Exec. Order No. 12333); 6 U.S.C. § 112 (2016) (applying the Common Rule to the research activities of Department of Homeland Security); 42 U.S.C. § 901 (2016) (the Social Security Administration remains subject to the regulations imposed upon the Department of Health and Human Services after separating in 1994).

140. See FEDERAL POLICY FOR HUMAN SUBJECTS, *supra* note 137.

141. See *id.* (“Human subject research conducted or supported by each federal department/agency is governed by the regulations of that department/agency.”).

142. Mark A. Rothstein, *Is Deidentification Sufficient to Protect Health Privacy in Research?*, 10 AM. J. BIOETHICS 3, 3–4 (2010).

problem of informed consent in the Common Rule suffers from the same problems inherent in other federal regulations in place—it does not directly answer the concerns raised by the public (i.e., the propriety of sharing de-identified samples) and has no real direct mechanism of enforcement (i.e., it is at best an incentive program). Any solution that fails to address these problems would be inadequate to maintain and support public confidence in newborn screening programs and the handling of residual blood samples by state officials.

Of course, the federal government could adopt more specific guidelines for when and how informed consent for the retention and use of residual samples is obtained and then simply rely on incentivizing state adoption of the federal government's position on the matter. There are already apt examples of this approach. For example, the Newborn Screening Saves Lives Act of 2007 permits the federal funding of outreach and education programs and establishes nationwide recommendations for newborn screening.<sup>143</sup> The Act does not discuss or establish protocols for obtaining informed consent for the storage of, or research conducted on, newborn blood samples.<sup>144</sup> Rather, the Act generally supports research aimed at improving newborn screening in federally funded activities.<sup>145</sup> Expanding the Act to include more complex and thoughtful standards for obtaining informed consent would be an excellent starting point, but again would not guarantee state compliance.

In past years, the federal government has appeared hesitant to take on the task of articulating clear and comprehensive national standards on the issues of retaining

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143. See Newborn Screening Saves Lives Act of 2007, Pub. L. No. 110-204, 112 Stat. 705 (codified as amended at 42 U.S.C. §§ 300b-8 to 300b-15 (2008)).

144. See generally *id.*

145. See § 7, 122 Stat. at 711-72 (codified as amended at 42 U.S.C. § 300b-15).

and experimenting with residual dried blood samples.<sup>146</sup> However, in 2010, the Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children published recommendations to help guide state policies on the storage and use of residual dried blood samples.<sup>147</sup> The Report presented eight specific recommendations, one of which was that "[a]ll state newborn screening programs should create policies that are in compliance with federal research regulations, assure that parents are aware of these activities, and consider whether documentation of parents' wishes and willingness to participate are required."<sup>148</sup> The report appears not to prescribe specific conditions for consent in the context at hand, and merely recommends that a policy be adopted that conforms to the tenants of the Common Rule.<sup>149</sup> It is perhaps the case that no specific, clear federal guidance is forthcoming in this area and, perhaps, no such guidance is appropriate or even necessary. Requiring informed consent may be more a matter of local public policy than of the law, in which case the question is one for the state political arena and not the national stage.

More recently, President Obama signed into law the Newborn Screening Saves Lives Reauthorization Act of 2014.<sup>150</sup> The Act reauthorizes federal grant programs that

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146. See Bob Bryan, *A Closer Look at Biobanking of Newborn Blood Spots*, GENOMICS L. REP. (July 1, 2009), <http://www.genomicslawreport.com/index.php/2009/07/01/a-closer-look-at-biobanking-of-newborn-blood-spots>.

147. SEC'Y'S ADVISORY COMM. ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN, BRIEFING PAPER: CONSIDERATIONS AND RECOMMENDATIONS FOR NATIONAL GUIDANCE REGARDING THE RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT SPECIMENS AFTER NEWBORN SCREENING 1, 24 (Sept. 2010), <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/briefingdriedblood.pdf>.

148. *Id.* at 4–5.

149. See *id.*

150. See generally Newborn Screening Saves Lives Reauthorization Act of 2014, Pub. L. No. 113-240, 128 Stat. 2851 (2014).

encourage newborn genetic screening, and supports related initiatives, but stipulates that the associated research is deemed human subjects research and prescribes some restrictions on the method by which informed consent can be obtained, including a prohibition on informed consent waivers.<sup>151</sup> These glacially slow movements of the federal government are steps in the right direction, but they do not fully balance the interests of states and the families of newborn infants, and (while serving as excellent guidance) do not guarantee that a state will utilize an effective informed consent model for their program for the reasons already stated above.

### B. *Balancing the Need for Informed Consent*

Testing for genetic illness is not always beneficial to the individual being tested. As Pellegrino points out, an excellent example of the tension between informed consent and the social value of genetic screening can be seen in the proposed testing of Huntington's disease.<sup>152</sup> "Huntington's is a late-onset neurological disorder, always fatal, and at present untreatable."<sup>153</sup> The offspring of an individual with Huntington's disease have a fifty percent chance of having the gene and the associated illness.<sup>154</sup> "Nancy Wexler has written with passion and eloquence on the tremendous complexity of the question of whether or not someone at risk for Huntington's should choose to be tested . . . [concluding] that there is no right decision for everyone, and that each

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151. *See id.*

152. EDMUND D. PELLEGRINO, PRESIDENT'S COUNCIL ON BIOETHICS, THE CHANGING MORAL FOCUS OF NEWBORN SCREENING: AN ETHICAL ANALYSIS 75 (2008).

153. *Id.*

154. *Id.*

person at risk must be allowed to make that decision for him or herself after reaching young adulthood.”<sup>155</sup>

Pellegrino points out, “As there is currently no treatment and no medical benefit from early detection, and a positive diagnosis is so potentially devastating, there has been widespread agreement that Huntington’s is one of the genetic disorders least suitable for routine screening, especially at birth or in early childhood.”<sup>156</sup> In many ways, forcing a person to learn of their inevitable decline in health impinges upon that individual’s autonomy.<sup>157</sup>

Moreover, the psychological toll that such knowledge may have on an individual diagnosed with a terminal, late-onset illness likely outweighs any benefit that knowledge would have for that person.<sup>158</sup> Individuals should have the option to remain free of the fears and apprehensions that accompany the heavy burden of knowing one’s fate.<sup>159</sup> In balancing the needs of individuals and society at large, the violation of an individual’s right to autonomy is frequently offset by the value of such knowledge guiding the treatment of that individual—particularly when it comes to infants. If that offset is missing, the activity is one which should be handled carefully and likely only with informed consent.

These same issues are not directly implicated by the storage and use of residual dried blood samples in non-diagnostic screening. However, understanding these concerns informs us that not all genetic screening is beneficial to the individual being screened and, sometimes, the mere knowledge of having a given gene can be

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155. *Id.* (citing Nancy S. Wexler, *The Tiresias Complex: Huntington’s Disease as a Paradigm of Testing for Late-Onset Disorders*, 6 *FASEB J.* 2820, 2824 (1992)).

156. *Id.* at 75–76.

157. *See id.* at 76.

158. *See id.* at 77.

159. *See generally id.*



detrimental to the wellness of that individual.<sup>160</sup> Any model of informed consent to widespread testing of a wide array of genetic illnesses must carefully account for the interests of the individual person being tested. It cannot be properly grounded in the interests of society at large or even that individual's local community, without a close nexus to the interests of the individual being tested. Accordingly, the ideal informed consent model will scale according to how close the connection is between the interests of the infant being screened and the proposed state action at issue.

On one end of the spectrum is genetic testing for a treatable illness the infant might have, while on the other end of the spectrum is genetic experimentation, which has no real connection to either the donor or the newborn screening program. As the proposed activity reaches the latter end of the spectrum, the need for informed consent is heightened, as the likelihood of constitutionality of the state action begins to wane.<sup>161</sup> The remainder of this Article is dedicated to describing the basic structure of an informed consent model that would address the various concerns discussed throughout this writing.

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160. It is worthwhile to note that having a gene associated with the development of an illness does not always necessarily entail the development of that illness. For example, mutations in the BRCA1 and BRCA2 genes, the expression of which helps regulate the repair of damaged DNA, do not necessarily lead to the development of breast cancer, while such mutations may greatly predispose an individual to illness. *See generally* Ass'n for Molecular Pathology v. Myriad Genetics Inc., 569 U.S. \_\_\_\_, 133 S. Ct. 2107 (2013) (deciding on the patentability of the BRCA1 and BRCA2 genes). As Pellegrino points out, "[o]nly a small proportion of the abnormal gene variants uncovered by newborn profiling will lead directly and inexorably to serious illness . . ." PELLEGRINO, *supra* note 152, at 76. "Typically, medically important SNPs [single nucleotide polymorphisms] will merely correlate (often in combination with other SNPs) with elevated susceptibilities for various medical conditions, and even these correlations will be unpredictable and highly variable, depending on a host of unknown factors." *Id.*

161. *See generally* Douglas Cty. v. Anaya, 694 N.W.2d 601, 601–08 (Neb. 2005).

### C. *Finding the Correct Model of Informed Consent*

In treading the murky waters of informed consent, it is important to bear in mind the lessons taught by the *Anaya* case.<sup>162</sup> Namely, *Anaya* demonstrates that states likely have the constitutional authority to collect newborn blood spots and then to use those blood spots in manner rationally related to public health and safety.<sup>163</sup> In considering issues of informed consent, it is therefore important to remind ourselves that states do not necessarily need informed consent for every conceivable use of residual newborn blood samples.

The “[e]lements of a traditional model of informed consent include an explanation of the proposed research, its purpose, a description of potential risks and benefits to the individuals participating, and a statement that participation is voluntary and can be discontinued at any time.”<sup>164</sup> Where participation can be lawfully made involuntary, it follows that informed consent would be unnecessary. However, gratuitously providing meaningful information to laypersons may nevertheless be a prudent policy for states when it comes to this area of public health and general welfare. Thus, it is important to distinguish between minimal standards and best practices when it comes to describing the ideal informed consent model.

In her 2011 article, Sandra J. Carnahan argues that all states should be required to obtain informed consent prior to the use of residual dried blood samples from state-mandated, genetic newborn screening, and presumed consent is an

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162. *See supra* Part II.B.

163. *See Anaya*, 694 N.W.2d at 608; *supra* Part II.B.; *see also* Sister Renée Mirkes, *Newborn Screening: Toward a Just System*, 22 ETHICS & MED. 163, 170 (2006).

164. Helen Swede et al., *National Population-Based Biobanks for Genetic Research*, 9 GENETICS MED. 141, 145 (2007).

inadequate solution.<sup>165</sup> Carnahan's approach, however, would create undue roadblocks to important genetic research for the sake of improving public confidence in the exercise of state power.<sup>166</sup> Beyond the incidents leading to the lawsuits in Texas, there is little data to suggest that any other states have used residual dried blood samples in the context of commercial gain.<sup>167</sup>

To the contrary, the most commonly reported uses for residual dried blood samples are actually much less ominous: some states utilize residual samples for confirmatory diagnosis (in an effort to avoid false positives) or for research aimed at improving the state's overall screening program.<sup>168</sup> Residual samples, for instance, are essential in understanding "[t]he full spectrum of a specific genetic disease" by allowing developers to determine "the range of severity of the disease, its incidence and genetic etiology in the general population and in subpopulations . . ."<sup>169</sup> Thus, while the controversy regarding newborn bloodspots, which arose in Texas, made national headlines, the perceived problem of profiteering at the expense of the privacy of citizens may be more of a tempest in a teapot.

Furthermore, the autonomy concerns implicated by the traditional underpinnings of informed consent are diminished with respect to infants, who do not make self-actualizing decisions with respect to their own medical

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165. See Carnahan, *supra* note 112, at 325–29.

166. See generally *id.*

167. Whether this lack of data is the result of underreporting or lack of occurrence is unclear.

168. See Kharaboyan et al., *supra* note 47, at 742 (listing the following uses for residual newborn blood spots: confirmatory diagnosis, quality assurance and public health needs, research use, clinical testing, and non-medical use).

169. AM. COLL. OF MED. GENETICS, POSITION STATEMENT ON IMPORTANCE OF RESIDUAL NEWBORN SCREENING DRIED BLOOD SPOTS (2009), <https://www.acmg.net> (select "Publications," select "Policy Statements").

care.<sup>170</sup> A parent's decision to volunteer the DNA samples of their children for research impinges upon an infant's autonomy no less and no more than a state's decision to do the same. To hold the contrary would be to conflate true autonomy concerns with the right of biological parents to make medical decisions for their children. As the *Anaya* court notes, the right of parents to make decisions for their children is not unfettered.<sup>171</sup> More importantly, such a right implicates a relatively low level of constitutional scrutiny.<sup>172</sup>

Nevertheless, there is merit in the claim that mandatory genetic research on all newborn samples *could* undermine public confidence in state-mandated genetic screening systems—especially given the bad publicity such programs have received in Minnesota and Texas.<sup>173</sup> This is particularly true of those programs that seek to utilize the dried blood samples in research unrelated to newborn screening or to otherwise share blood samples with third-party research entities.<sup>174</sup> Different uses implicate different issues. It follows that different uses warrant a tiered approach that blends the presumed and informed consent approaches, while

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170. See generally Christopher M. O'Connor & Kevin N. Lorah, *Dilemmas at the Beginning of Life: Biomedical Ethics in the Newborn*, 3 J. LANCASTER GEN. HOSP., Fall 2008, at 102 ("Across the country, it is well settled that the parents are the decision-makers for the newborn. Yet, in extreme cases, states have the ability to usurp parental authority. Less settled, however, is the degree to which parents' moral and religious beliefs should influence treatment decisions.").

171. *Douglas Cty. v. Anaya*, 694 N.W.2d 601, 608 (Neb. 2005).

172. See *id.*

173. See generally Beth A. Tarini, *Storage and Use of Residual Newborn Screening Blood Spots: A Public Policy Emergency*, 13 GENETICS MED. 619, 620 (2011) (commenting that while the matter is often discussed in terms of law and ethics, there is a greater concern regarding public policy and perception of governmental action) [hereinafter Tarini, *Storage and Use*].

174. See, e.g., Rob Stein, *Newborns' Blood Samples Are Used for Research Without Parents' Consent*, WASH. POST (June 30, 2009), <http://www.washingtonpost.com/wpdyn/content/article/2009/06/29/AR2009062903118.html>; J. Scott Applewhite, *Debate Over Blood Samples from Babies*, USA TODAY (Feb. 9, 2010), [http://usatoday30.usatoday.com/news/health/2010-02-08-baby-blood\\_N.htm](http://usatoday30.usatoday.com/news/health/2010-02-08-baby-blood_N.htm).

recognizing the sovereign authority of the states to make important decisions to advance the health and safety of their citizens.

States should openly utilize residual newborn blood samples in confirmatory screening and for research aimed at maintaining the very screening program that administers the testing. They should also require informed consent for such practices only to the extent that state policy deems appropriate for ensuring public confidence.<sup>175</sup>

While we found that the vast majority of parents were willing to permit the state to store their children's [newborn blood spot] samples, 22% of parents were not willing to permit storage of their children's [newborn blood spot] samples. Non-participation of this magnitude could create problems in using the [newborn blood spot] blood samples either for ongoing program evaluation (e.g., [newborn blood spot] candidate test validity studies) or for future research studies that rely on the population representation of this sample collection.<sup>176</sup>

Research related to maintaining the overall integrity and quality of a newborn genetic screening program would likely be found rationally related to a state's goal of advancing public health and safety, and consequently fall within a state's regulatory powers.<sup>177</sup> To that end, informed consent should not be strictly required for confirmatory diagnoses or for use in research aimed at improving or calibrating the originating state's screening program. In any event, public confidence in newborn screening programs would remain relatively unphased by state-run research that ultimately

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175. See generally Bradford L. Therrell, Jr. 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, 622 (2011) ("State policies also should emphasize transparency of administrative practices and create supporting information that encourages informed public participation.").

176. Beth A. Tarini et al., *Not Without My Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research*, 13 PUB. HEALTH GENOMICS 125, 129 (2010).

177. See, e.g., *Spiering v. Heineman*, 448 F. Supp. 2d, 1129, 1140 (D. Neb. 2006); *Anaya*, 694 N.W.2d at 608.

ensures the continued improvement and operation of such programs.

However, at a minimum, states should presume parental consent, but allow for opt-outs, with respect to the sharing of de-identified residual newborn blood samples with third-parties or the use of such samples in unrelated research.<sup>178</sup> The doctrine of presumed consent operates on a notion that if the individual infant could volunteer their sample, they would, or perhaps more aptly, that parents would allow the de-identified samples to be used in unrelated scientific research.<sup>179</sup> This approach strikes a compromise. The samples, at this point, would have already been lawfully acquired by the state.<sup>180</sup> They would be de-identified and, hence, no longer subject to the Common Rule.<sup>181</sup> The samples would, in effect, be bio-waste with no identifiable individual stake-holders other than the state.<sup>182</sup>

States should always obtain informed consent prior to use, or disclosure to third-parties, of any identifiable newborn blood samples and should refrain from bartering or

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178. Opt-out approaches should be utilized with caution, however, as they threaten the reliability of research studies through selection bias. Kharaboyan et al., *supra* note 47, at 747. Nevertheless, “[r]esearch suggests that denying parents an opportunity to provide their permission—whether through opt-in or opt-out mechanisms, written or verbal—is likely to damage public support causing programs to lose both the battle and the war.” Tarini, *Storage and Use*, *supra* note 173, at 620.

179. See Carnahan, *supra* note 112, at 326–27.

180. See *supra* Part II.A.

181. Rothstein, *supra* note 142, at 3.

182. See generally ALISSA JOHNSON ET AL., CURRENT STATE PRACTICES AND POLICIES ON THE STORAGE AND USE OF NEWBORN SCREENING SAMPLES (2010), <https://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/Research/GenomicBasedResearch/Commissioned%20Reports/State%20Practice-Policy%20Residual%20DBS%20IOM%20-%20approved.pdf> (“Laws and regulations in California, Maine, Utah and Washington declare that newborn screening specimens are the property of the state.”).

selling samples for commercial gain.<sup>183</sup> Identification is at the heart of privacy concerns and would likely lead to significant public outcry.<sup>184</sup> Similarly, the systematic appropriation of genetic materials for gain has and would likely again lead to significant public pushback.<sup>185</sup> While one might argue that with parental informed consent the practice would be legal, it would nevertheless be unwise and, ultimately, likely to instigate litigation. Furthermore, there is too great a risk that openly allowing such practices will lead to the exploitation of newborns, whose interests need to be zealously safeguarded both by parents and society at large.<sup>186</sup> Given the lack of benefit to the newborn, and the high likelihood of public outcry, these practices should be avoided where possible and always mitigated with cautiously obtained informed consent.

Of course, employing a tiered method, which makes compromises, will likely still incite public criticism, but any state action will have its detractors. There was, in fact, some criticism of Indiana's mere storage of such samples.<sup>187</sup> Since at least 1991, the Indiana State Department of Health has been collecting blood samples from newborn infants and storing the residual samples for potential later use in research.<sup>188</sup> As of 2014, it was estimated that the cache contained somewhere between 2.25 and 2.5 million samples,

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183. See Carnahan, *supra* note 112, at 300–01; Drabiak-Syed, *supra* note 136, at 1, 3; Tarini, *Storage and Use*, *supra* note 173, at 620.

184. See generally Carnahan, *supra* note 112; Drabiak-Syed, *supra* note 136; Tarini, *Storage and Use*, *supra* note 173.

185. See, e.g., *Bearder v. State*, 806 N.W.2d 766, 769 (Minn. 2011); First Amended Complaint, *Beleno v. Tex. Dep't of State Health Servs.*, No. SA-09-CA-0188-FB, 2009 WL 5072239 (W.D. Tex. Sept. 29, 2009).

186. See O'Connor & Lorah, *supra* note 170.

187. See *Indiana Stored Babies' DNA, Blood for Research Without Parental Consent*, RT (July 14, 2014, 2:29 AM), <https://www.rt.com/usa/172208-indiana-baby-blood-samples>.

188. *Id.*

contained in 666 bankers boxes.<sup>189</sup> No parental consent has been obtained for such research and, accordingly, it appears Indiana has not allowed the samples to be used in this manner.<sup>190</sup>

Yet, the very notion that a state would consider such research has generated negative commentary by the public.<sup>191</sup> “I’m curious why they didn’t share that,’ Mallory Ervin, the mother of a 4-year-old named Theo, said. ‘It now makes me think “what are they hiding?” As a parent, I’d absolutely like to know.’”<sup>192</sup> Public confidence is a fickle thing and, while it is important to consider in striking the right balance in shaping policy, it cannot be the only consideration. For years, Indiana collected and stored these samples without any concrete plan on when and how to use these samples.<sup>193</sup> As a result, Indiana never obtained informed consent and, years later, acknowledge the struggle with deciding how to proceed.<sup>194</sup> “No, we did nothing to notify parents,’ Bob Bowman, director of [Indiana State Department of Health’s] Genomics & Newborn Screening Program, said to the Indiana NBC affiliate. ‘That’s why we are struggling right now to try to figure out what is the best and most appropriate thing to do.’”<sup>195</sup>

Ultimately, as of June of 2013, the Indiana Genomics and Newborn Screening Program adopted a notification policy that now seeks parental consent for possible future

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189. *Id.*

190. *Id.*

191. *See id.*

192. *Id.*

193. *See id.*

194. *See id.*

195. *Id.*



research.<sup>196</sup> If parents elect to opt out of future research activities, the State of Indiana does not store the dried blood samples and instead destroys them.<sup>197</sup> With respect to samples obtained prior to enactment of the 2013 policy update, Indiana permits guardians to request the destruction of previously stored dried blood samples by having them send in a written form that can be obtained on the State's website.<sup>198</sup>

The newer processes adopted in Indiana are an improvement on the State's past practices, and while it does not fully account for the potential trespass of having stored dried blood spots for years without informed consent, it does address many of the major concerns that arise with the disposition of residual newborn blood samples. The difficult questions faced by Indiana could have been avoided by adopting the notification policy much sooner, and this should serve as a cautionary tale to any states that have not yet incorporated a clear informed consent policy.<sup>199</sup>

### CONCLUSION

It is certainly possible that as technology develops, the list of newborn blood spot related activities warranting informed consent may continue to grow. However, the controversies catching the most media attention in this area have focused on those concerns discussed in Part III. The diversity of these issues illustrates that the "best" approach to dealing with the conundrum of informed consent in the context of newborn screening will constrict state power no further than necessary, while simultaneously curtailing those activities that are most offensive to the public

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196. *See id.*; *Newborn Screening Home: Newborn Screening Dried Blood Spot*, IND. ST. DEP'T HEALTH, <http://www.in.gov/isdh/20215.htm> (last visited Apr. 25, 2016).

197. *Newborn Screening Home*, *supra* note 196.

198. *Id.*

199. *See generally id.*

conscience.<sup>200</sup> A vehicle for encouraging national uniformity in the handling of residual samples has not emerged, but when it does, the country needs to be ready for a complex solution to a complex problem.<sup>201</sup>

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200. *See supra* Part III.

201. *See supra* Part III.B.

