

## LEGAL REGULATION OF BANKING NEWBORN BLOOD SPOTS FOR RESEARCH: HOW *BEARDER* AND *BELENO* RESOLVED THE QUESTION OF CONSENT

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### I. INTRODUCTION

Since 1965, newborns at birth receive a neonatal heel prick to collect blood for conducting newborn screening tests.<sup>1</sup> After collection, the newborn blood spot (NBS) samples are sent to the respective state health department for testing, retained for varying lengths of time, and in some cases used for further research purposes.<sup>2</sup> Most states do not inform parents that the state health department will retain or conduct research using their infant's NBS following the screening process.<sup>3</sup>

In this article, I argue that retention and subsequent research projects constitute "human subjects research," should be governed under the Common Rule, and that a waiver of consent does not appropri-

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<sup>1</sup> Linda Kharaboyan et al., *Storing Newborn Blood Spots: Modern Controversies*, 32 J.L. MED. & ETHICS 741, 741 (2004).

<sup>2</sup> Richard S. Olney et al., *Storage and Use of Residual Dried Blood Spots from State Newborn Screening Programs*, 148 J. PEDIATRICS 618, 618-19 (2006).

<sup>3</sup> *Id.* at 621.

ately protect subjects' interests.<sup>4</sup> Examining the status of NBS collection and research use is important because the federal government has indicated its intent to facilitate research sharing of NBS from each state health department,<sup>5</sup> yet it has not classified the collection and subsequent research use of the NBS samples as human subjects research nor afforded it corresponding protections by addressing whether the Common Rule would apply.<sup>6</sup> Federal guidance related to the sample and its associated information does not fully clarify existing questions of how to apply federal regulations, but rather provides conflicting interpretations of whether use of the sample should be governed under the Common Rule.

This federal regulatory uncertainty is further compounded by how each state addresses NBS retention and research.<sup>7</sup> As states expand their retention and sharing of NBS for research and respond to recent federal initiatives, state health departments will be faced with this uncertain landscape of federal regulation under the Common

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<sup>4</sup> Basic Health and Human Services (HHS) Policy for Protection of Human Research Subjects states "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Protection of Human Subjects: Definitions, 45 C.F.R. § 46.102(d) (2009); *see also* Aaron Goldenberg, *Ethics at the Crossroads of Public Health and Biobanking: The Use of Michigan's Residual Newborn Screening Bloodspots for Research*, 13-14 (Jan. 2009) (unpublished Ph.D. dissertation, Case Western Reserve University) available at <http://drcdev.ohiolink.edu/handle/123456789/5733>. Goldenberg states:

[W]hen the intention of surveillance is to collect information on the prevalence or incidence of a disease in order to improve a targeted program, then it is considered practice. However, if a goal of a program is to collect and disseminate 'generalizable' knowledge, then it should be considered a research activity . . . . The biobanking of NBS bloodspots could cloud this distinction between practice and research even further as samples collected in a practice oriented public health service are used for unspecified future research purposes.

*Cf.* Mary Lou Lindegren et al., Conference Slides from Banking Newborn Dried Blood Spots for Public Health Conference: Developing a Strategic Plan to Assess the Feasibility, Utility, and Practical Implementation of Establishing a National/Multi-state Bank of Leftover Newborn DBS, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 2002), <http://www.cdc.gov/genomics/events/file/print/spotbanktalkMLL.pdf> (outlining recommendations for use of NBS banks in research and public health); Newborn Screening Saves Lives Act of 2007, Pub. L. No. 110-204, 122 Stat. 705, 710-11 (2008) (continuing expansion of research in newborn screening).

<sup>5</sup> *See* Newborn Screening Saves Lives Act of 2007, *supra* note 4, at 709.

<sup>6</sup> Public Welfare: Protection of Human Subjects, 45 C.F.R. § 46 (2009).

<sup>7</sup> *See* Olney et al., *supra* note 2, at 619-21.

Rule and federal guidance documents.<sup>8</sup> Accordingly, state health departments will need to turn to their state laws governing the collection of NBS for research purposes for more specific direction. State statutes vary widely with regard to how to treat NBS retention and research, as well as what, if any, information they provide to the parents to inform them of the NBS storage and subsequent uses.<sup>9</sup> This article will briefly describe how several states approach these issues and discuss recent litigation in Minnesota and Texas that addressed issues of consent and privacy. Several of these elements raised in recent litigation also echo recent survey research about the general public's attitudes relating to their willingness to contribute NBS for research purposes with or without consent.<sup>10</sup>

Finally, I will assert that using NBS for research purposes requires us to re-examine how to better protect the ethical principles underpinning the Common Rule. This requires re-interpretation of the legal meaning of "identifiability" and precludes circumventing consent requirements by sample anonymization. I argue that informed consent should be required for both storage and research following the screening process, and parents should retain the right to refuse their infant's participation in the state's biobank despite the potentially great social benefit derived from the sample.

## II. NEWBORN SCREENING AND RETENTION

Newborn screening and NBS sample retention represents the largest genetic testing and screening program in the United States, with broad collection across varied population demographics.<sup>11</sup> Tra-

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<sup>8</sup> See Newborn Screening Saves Lives Act of 2007, *supra* note 4; 45 C.F.R. § 46; Barbara J. Evans & Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens*, 27 J. LEGAL MED. 119, 119-22 (2006).

<sup>9</sup> See generally CITIZENS COUNCIL ON HEALTHCARE, STATE BY STATE NEWBORN BLOOD & BABY DNA RETENTION PRACTICES, [hereinafter CITIZENS COUNCIL ON HEALTHCARE], available at [http://www.cchconline.org/pdf/50\\_States-Newborn\\_Blood\\_Retention\\_Policies\\_FINAL.pdf](http://www.cchconline.org/pdf/50_States-Newborn_Blood_Retention_Policies_FINAL.pdf) (last visited Apr. 26, 2010).

<sup>10</sup> See Stephen J. O'Brien, *Stewardship of Human Biospecimens, DNA, Genotype and Clinical Data in the GWAS Era*, 10 ANN. REV. GENOMICS HUM. GENETICS 193, 197-200 (2009).

<sup>11</sup> Kharaboyan et al., *supra* note 1, at 747. For the purpose of this article, my own arguments

ditionally, state health departments have stored NBS for confirmatory diagnosis and quality assurance testing, but recently researchers have become interested in banking NBS for research on the genetic underpinning of disease and gene-environment interactions.<sup>12</sup> Most states do not require parental consent to collect a sample for screening based on a harm-reduction model to prevent potential medical injury to newborns.<sup>13</sup> Accordingly, many state health departments do not obtain consent to collect and analyze NBS, nor to store and use the NBS for further research.<sup>14</sup> *Science* magazine has referred to this "treasure trove of samples" as a "science gold mine."<sup>15</sup> Storage and research use of NBS raises a set of legal and ethical questions related to consent and privacy that should be analyzed within the framework of federal law designed to regulate human subjects research as well as federal and state law governing newborn screening programs.<sup>16</sup>

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relating to obtaining consent refer to prospectively collected samples for retention and research. See also Jeffrey R. Botkin, *Research for Newborn Screening: Developing a National Framework*, 116 PEDIATRICS 862, 862 (2005); CITIZENS COUNCIL ON HEALTHCARE, *supra* note 9, at 3.

<sup>12</sup> Kharaboyan et al., *supra* note 11, at 742. See also CITIZENS COUNCIL ON HEALTHCARE, *supra* note 9, at 3.

<sup>13</sup> See Goldenberg, *supra* note 4, at 82, 86.

<sup>14</sup> Goldenberg, *supra* note 4, at 71 tbl.3, 86. Goldenberg also notes that the collection of NBS can be distinguished from the retention of biological materials from surgical or other medical procedures because in those instances a patient at least consents to the procedure, may be informed that leftover biological materials become hospital property, and some institutions may provide the patient an opportunity to opt-out. *Id.* at 86.

<sup>15</sup> Jennifer Couzin-Frankel, *Science Gold Mine, Ethical Minefield*, 324 SCI. 166, 166 (2009).

<sup>16</sup> This section of the article will focus on federal law found in 45 C.F.R. § 46 (2009), known as the Common Rule. The FDA contains an additional set of regulations governing the treatment of human subjects in FDA-regulated clinical investigations. State law provides additional requirements and definitions that will be discussed in the following sections. Protection of Human Subjects, 21 C.F.R. § 50 (2009); Institutional Review Boards, 21 C.F.R. § 56 (2009); Investigational Device Exemptions, 21 C.F.R. § 812 (2009). See generally Evans & Meslin, *supra* note 8, at 119.

### III. FEDERAL LAW AND INTENDED PURPOSE<sup>17</sup>

#### Common Rule

The Common Rule sets out U.S. federal policy for the protection of human subjects involved in research conducted or supported by federal agencies or departments.<sup>18</sup> Under the Common Rule, individuals are considered human research subjects if an investigator conducting research obtains “(1) data through intervention or interaction with the individual, or (2) identifiable private [health] information.”<sup>19</sup> Pre-existing information and data whose source cannot be identified by the investigator are exempt from the Common Rule’s requirements.<sup>20</sup> Current discussion centers around considerations of whether a state health department’s use or sharing of NBS for research constitutes “research” and whether the investigator can readily identify the individual to whom the sample pertains.<sup>21</sup>

Based on this uncertainty, some state health departments may follow the Office for Human Research Protections (OHRP) Guidance on Research Involving Coded Private Information or Specimens (OHRP Guidance) as a means of interpreting the Common Rule’s applicability.<sup>22</sup>

OHRP [Guidance] does not consider research involving only coded private information or specimens to involve human subjects as defined under 45 C.F.R. § 46.102(f) if the following conditions are both met: (1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and (2) the inves-

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<sup>17</sup> Although the HIPAA Privacy Rule may apply, this discussion is limited to the collection and research use of the sample itself and does not address the associated protected health information. See General Administrative Requirements: Definitions, 46 C.F.R. § 160.103 (2010); Security and Privacy, 46 C.F.R. § 164 (2010).

<sup>18</sup> Public Welfare: Protection of Human Subjects, 45 C.F.R. § 46 (2009).

<sup>19</sup> Protection of Human Subjects: Definitions, 45 C.F.R. § 46.102 (2009).

<sup>20</sup> See Katherine Drabiak-Syed, *State Codification of Federal Regulatory Ambiguities in Biobanking and Genetic Research*, 30 J. LEGAL MED. 299, 300 (2009).

<sup>21</sup> See DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR SPECIMENS (Oct. 16, 2008), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.

<sup>22</sup> *Id.*

tigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain . . . .<sup>23</sup>

Thus, newborns providing a blood sample would be considered human research subjects if their blood is (1) “collected for an identified research project or (2) [their] information is readily identifiable by the investigator.”<sup>24</sup> This raises the questions of whether the NBS samples were collected with the intention to bank them at the state health department, whether this banking constitutes a research project, and whether the infants’ information is readily identifiable by the investigators using the NBS.

These issues pose several considerations for state health departments. Currently, state health departments collect NBS with screening as the primary purpose, but collection also serves as the mechanism for creating a biobank or disseminating the samples for additional specific research projects.<sup>25</sup> When health departments initially collect the NBS samples, they are accompanied by identifiers and stored in the department even if no further research occurs.<sup>26</sup> Some programs may later de-identify the samples and retain the code to re-link them for internal research, and some programs may provide the use of these samples to associated researchers.<sup>27</sup> Thus, at the time of collection and banking, the samples were identifiable to personnel at the health department.<sup>28</sup> Accordingly, collection of samples for NBS banks—whether intended only for placement in the state health department biobank or additional specified research projects—should be governed by the Common Rule.<sup>29</sup>

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<sup>23</sup> *Id.*

<sup>24</sup> See Jennifer Girod & Katherine Drabiak, *A Proposal for Comprehensive Biobank Research Laws to Promote Translational Medicine in Indiana*, 5 *IND. HEALTH L. REV.* 217, 220 (2008); Protection of Human Subjects: Definitions, 45 *C.F.R.* § 46.102.

<sup>25</sup> See Mary Kay Pelias & Nathan Markward, *Newborn Screening, Informed Consent, and Future Use of Archived Tissue Samples*, 5 *GENETIC TESTING* 179, 179 (2001); Lindegren et al., *supra* note 4.

<sup>26</sup> Pelias & Markward, *supra* note 25, at 181.

<sup>27</sup> *Id.* at 182.

<sup>28</sup> *Id.*; See Goldenberg, *supra* note 4, at 28 (“[O]nly two states’ samples are completely devoid of identifiers.”).

<sup>29</sup> Goldenberg’s research examined how stakeholders in the Michigan Neonatal BioTrust viewed research on NBS. Goldenberg, *supra* note 4, at 81. Some viewed the research on NBS

Currently, an Institutional Review Board (IRB) may waive application of the Common Rule if (1) the research involves minimal risk, (2) the variance from normal consent will not affect subjects' rights and welfare, (3) absent such variance, the research could not practicably be done, and (4) additional pertinent information will be provided to subjects after participation when appropriate.<sup>30</sup> Several issues may preclude fulfilling these waiver requirements. First, research using NBS samples may not necessarily be classified as involving minimal risk to the subjects from the subjects' perspective (as represented by their parents or guardians). NBS samples are capable of producing whole genome DNA and genome-wide scans.<sup>31</sup> Recent studies indicate the potential for data attack.<sup>32</sup> An attack may occur in several ways, such as identifying the presence of an individual participant in genome-wide association studies (GWAS) by analyzing the allele frequencies of a large number of single nucleotide polymorphisms (SNPs) or by looking at published statistics to find participants' SNPs.<sup>33</sup> This discovery suggests that the low level of risk associated with even de-identified samples must be reassessed, given the potential for identification using attack methodology, and that the use of NBS in such studies would constitute more than minimal risk.<sup>34</sup> Also, identification could affect the newborns' rights and wel-

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as merely formalizing existing health department procedures that incorporate research as an extension of the screening program. *Id.* Other stakeholders viewed research using NBS that would be derived from the BioTrust as separate research protocol. *Id.* I argue that even if a state's health department banks and uses the NBS for additional internal research following screening, these actions should constitute "research" under the Common Rule.

<sup>30</sup> Protection of Human Subjects: General Requirements for Informed Consent, 45 C.F.R. § 46.116(d) (2010).

<sup>31</sup> See Mads Hollegaard et al., *Genome-wide Scans Using Archived Neonatal Dried Blood Spot Samples*, 10 BMC GENOMICS 297, 4–6 (2009).

<sup>32</sup> See Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, 4 PUB. LIBR. SCI. GENETICS e1000167 (2008).

<sup>33</sup> A full discussion of how attack or potential identification of individuals in GWAS studies affects identifiability is outside the scope of this article. See generally Homer et al., *supra* note 32; Kevin B. Jacobs et al., *A New Statistic and Its Power to Infer Membership in a Genome Wide Association Study Using Genotype Frequencies*, 41 NATURE GENETICS 1253 (2009).

<sup>34</sup> Stephen J. O'Brien, *Stewardship of Human Biospecimens, DNA, Genotype, and Clinical Data in the GWAS Era*, 10 ANN. REV. GENOMICS & HUM. GENETICS 193, 201 (2009) (proposing to reassess how we apply federal law relating to composite genotype data).

fare if their identities are linked with a particular condition, causing them future anxiety, stigma, or discrimination.<sup>35</sup> Further, both public attitudes and litigation discussed below suggest that retaining and using NBS absent consent affects subjects' rights and welfare because it raises issues of their legal and dignitary rights. Developing a consent procedure, though it may initially pose costs and possible administrative burdens, is not necessarily impracticable.<sup>36</sup> Sweden, for example, has instituted an explicit consent policy required for NBS sample retention and research use.<sup>37</sup> The Swedish model demonstrates that requiring consent is not incapable of being put into practice and can still result in amassing a large, richly annotated collection for research.<sup>38</sup>

The waiver of consent requires fulfilling all four factors listed above.<sup>39</sup> I assert that this recent data related to attack in GWAS studies removes NBS research from the minimal risk category, that variance from consent will affect subjects' rights and welfare, and that absent such variance it is not impracticable to carry out the research of forming a biobank within a state health department. Accordingly, I argue that an IRB should not waive application of the Common Rule to the collection of NBS, but actual consent should be obtained from the newborns' parent or guardian for research following the screening process.

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<sup>35</sup> See generally Mark A. Rothstein, *GINA, the ADA, and Discrimination in Employment*, 36 J. L. MED. & ETHICS 837, 839 (2009) (concluding that despite general prohibitions against genetic discrimination by insurer and employers in the Genetic Information Nondiscrimination Act of 2008 (GINA), GINA does not provide complete protection and contains notable gaps in applicability).

<sup>36</sup> See Lisa Feuchtbaum et al., *Questioning the Need for Informed Consent: A Case Study of California's Experience with a Pilot Newborn Screening Research Project*, 2 J. EMPIRICAL RES. ON HUM. RES. ETHICS 3, 10-11 (2007).

<sup>37</sup> See Lisa Edwards, *Tissue Tug-of-War: A Comparison of International and U.S. Perspectives on the Regulation of Human Tissue Banks*, 41 VAND. J. TRANSNAT'L L. 639, 662 (2008). Sweden collects coded, richly annotated NBS samples and stores them at the Karolinska Institute's biobank. Sweden requires explicit consent to store and use the NBS for research, requires additional consent for each research project, and requires retroactive consent to use existing samples that were obtained without consent. See *id.*

<sup>38</sup> *Id.* at 661-62.

<sup>39</sup> Protection of Human Subjects: General Requirements for Informed Consent, 45 C.F.R. § 46.116(d).



#### IV. FEDERAL NEWBORN SCREENING INITIATIVES

Several initiatives within the federal government have recently addressed the issue of NBS collected for retention and further research.<sup>40</sup> These actions recognize the potentially beneficial uses of NBS and are designed to facilitate their research use.<sup>41</sup> Despite these objectives, these initiatives have not yet, but must, clarify that the collection of NBS for banking constitutes human subjects research, and the collection practices should be governed accordingly.

In 2008, Congress passed the Newborn Screening Saves Lives Act (Act), designed to promote and improve newborn screening for heritable disorders, develop population research surveillance and epidemiology, and expand research partnerships within the government as well as academic and private institutions.<sup>42</sup> The Act will unify and nationalize the data collection resulting from state screening programs by standardizing data collection and reporting into a coordinated surveillance system to record and track newborns with a genetic, heritable, or metabolic disorder.<sup>43</sup> Section 1116 describes the Hunter Kelly Research Program, designed to expand research using NBS samples “for additional newborn conditions and other genetic, metabolic, hormonal, or functional conditions that can be detected through newborn screening . . . .”<sup>44</sup> If this portion of the program is interpreted in keeping with the purpose of the Act, then this additional research will be conducted by state health departments, as well as researchers from academic and private institutions. This portion of the Act does not specify the protocol for sharing the NBS for these expanded research projects and whether the newborn’s information is linked or linkable to the NBS sample.<sup>45</sup> Despite comprehensive discussion of research objectives, the Act contains no section specifically discussing regulatory compliance on the issue of consent to use the NBS samples or associated medical information for these research

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<sup>40</sup> See, e.g., Newborn Screening Saves Lives Act of 2007, *supra* note 4.

<sup>41</sup> See Olney et al., *supra* note 2, at 621-22.

<sup>42</sup> Newborn Screening Saves Lives Act of 2007, *supra* note 4.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at § 1116.

<sup>45</sup> See *id.* at § 1116.

projects.<sup>46</sup>

In 2005, the CDC developed the Newborn Screening Translation Research Initiative (NSTRI), designed to facilitate the creation of a biobank available for research, including the development of screening technologies.<sup>47</sup> Currently, the bank consists of samples derived from commercial blood banks and cord blood banks, but the CDC previously indicated its intent to collect and bank NBS from state health departments.<sup>48</sup> The CDC noted that over 95% of NBS samples are retained by states for some period of time following screening and the CDC seeks to establish the bank to study “population-based data on prevalence of gene variants of public health significance, and the association of gene variants with disease and risk factors.”<sup>49</sup> The NSTRI works to understand how genetic and biochemical differences that occur within the population can be used to improve newborn screening.<sup>50</sup> An asterisk following this goal notes that this research using banked samples is not limited to understanding and improving new-

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<sup>46</sup> *Id.* In a statement given to the Association of American Physicians and Surgeons, Inc., Rep. Ron Paul expressed his disapproval of the then Senate Bill 1858, stating that it exceeded constitutional limitations and expressing concern that the government would have access to all medical records via the registry and tracking system without consent. Rep. Paul noted that confidentiality is a key component to physician-patient privacy, and the Act would betray patients’ trust by compiling private medical information into a database without consent. 154 CONG. REC. E550-51 (daily ed. Apr. 9, 2008) (statement of Rep. Paul), available at <http://www.aapsonline.org/legis/pauls1858.php> (last visited Nov. 6, 2010); Newborn Screening Saves Lives Act of 2007, *supra* note 4.

<sup>47</sup> *Newborn Screening and Molecular Biology Branch*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/nceh/dls/nsmbb.html> (last visited Nov. 6, 2010). An email from CDC Public Inquiries dated December 30, 2009 stated that the “CDC does not maintain a biobank of newborn blood spots” but that it collaborates with state public health programs to conduct research. At the completion of such studies the remaining samples are returned to the health department. Email from Centers for Disease Control and Prevention Public Inquiries (Dec. 30, 2009, 4:53PM CST) (on file with author) (hereinafter Email from CDC Public Inquiries).

<sup>48</sup> Email from CDC Public Inquiries, *supra* note 47; Lindegren et al., *supra* note 4.

<sup>49</sup> *Banking Newborn Blood Spots for Public Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Sept. 23-24, 2002), <http://www.cdc.gov/genomics/events/conference/spotBank/index.htm> (last updated, Mar. 31, 2010).

<sup>50</sup> See *Newborn Screening Laboratory Bulletin*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 2008), <http://www.cdc.gov/nbslabulletin/bulletin.html> (click on “Next Generation Newborn Screening”).

born screening, but also seeks to achieve “a better understanding of the disease process” by collaborating with research partners on the federal and state level.<sup>51</sup>

To summarize, the CDC has indicated its intent to organize a national biobank as a resource to conduct both newborn screening test research and broad genetic and biochemical research by forming academic and corporate partnerships.<sup>52</sup> Currently, the CDC states that the bank does not contain NBS samples from state health departments but has previously indicated that it may in the future.<sup>53</sup> An email communication from the CDC clarified that, although banked samples are available for research within the NSTRI, NBS samples are not currently available to researchers.<sup>54</sup> The CDC noted that “a number of significant issues need to be addressed before any widespread use [of the banked samples] can begin,” listing challenges such as supply limitations and methodological concerns, but neglecting to mention any ethical issues related to the source of the samples.<sup>55</sup> Although the CDC thoroughly discusses its goals to facilitate research using NBS, its failure to discuss the pertinent regulations or ethical implications constitutes a critical shortcoming.<sup>56</sup>

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<sup>51</sup> *Id.* Email from CDC Public Inquiries, *supra* note 47, clarified that currently the CDC does not make the NBS samples available to any researchers, but also states that “state . . . newborn screening programs are encouraged to explore potential collaboration with the NSTRI in areas of mutual interest” and NSTRI collaborates with health departments to conduct epidemiological studies.

<sup>52</sup> See CTFS. FOR DISEASE CONTROL & PREVENTION, *supra* note 50. Newborn Screening Laboratory Bulletin, *Future Directions*, <http://cdc.gov/nbslabbulletin/bulletin.html> (last visited Mar. 8, 2010).

<sup>53</sup> Lindegren et al., *supra* note 4; Email from CDC Public Inquiries, *supra* note 47.

<sup>54</sup> It is unclear whether the CDC’s clarification means NBS are not available to outside researchers but are available to affiliated research partners through the NSTRI. Email from CDC Public Inquiries, *supra* note 47.

<sup>55</sup> See CTFS. FOR DISEASE CONTROL & PREVENTION, *supra* note 50; Email from CDC Public Inquiries, *supra* note 47.

<sup>56</sup> See Lindegren et al., *supra* note 4.

## V. GUIDANCE AND RECOMMENDATIONS FOR THE DISPOSITION OF NBS SAMPLES

Both federal agencies and national medical associations recognize that the uncertainty of federal regulations, as well as burgeoning federal initiatives to promote collection of NBS samples for banking research, requires clarification of how this collection for research is classified and governed.<sup>57</sup>

In August 2009, the U.S. Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) issued a summary of recommendations relating to storage and use of NBS samples.<sup>58</sup> Importantly, it referred to the collection of residual NBS samples as a biobank and states that the Common Rule governs.<sup>59</sup> ACHDNC noted that collection and banking policies should assure respect for the privacy and confidentiality of families.<sup>60</sup> It also recommended that each state disseminate policies that promote public trust, emphasize transparency, and encourage informed public participation.<sup>61</sup> It recommended that all states should have a policy in place to address NBS sample retention and use.<sup>62</sup> This policy should address research access and use of samples; provide educational materials to the public and expecting mothers on use and potential future uses; adopt an opt-in or opt-out model if the samples are available for any process outside the screening process; and assess the utility of the opt-in or opt-out process.<sup>63</sup>

Although the recommendations intend to promote public trust

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<sup>57</sup> See Brad Therrell et al., *Briefing Paper: Considerations and Recommendations for a National Policy Regarding the Retention and Use of Dried Blood Spot Specimens after Newborn Screening*, RESOURCE REPOSITORY.ORG (2009), <http://resourcerepository.org/documents/1681/briefingpaper:considerationsandrecommendationsforanationalpolicyregardingtheretentionanduseofdried-bloodspotspecimensafternewborns/> (click on article title; click "I agree").

<sup>58</sup> See generally *id.* at 1-3.

<sup>59</sup> *Id.* at 1, 3.

<sup>60</sup> *Id.* at 1.

<sup>61</sup> *Id.*

<sup>62</sup> Therrell et al., *supra* note 57, at 1.

<sup>63</sup> *Id.* at 2-3. The recommendations define that including internal test development of screening tests falls within the definition of the screening process. *Id.* at 3.

and encourage participation, several of the classifications and resulting proposals strike an unbalanced compromise between promoting research and honoring ethical principles. Classifying the collection as a biobank means that the Common Rule should govern and the researcher should obtain consent where the newborn's information is readily identifiable by the investigator. If the sample is linked or linkable with identifiers by the investigator, then actual consent should be required. However, even if the sample is not linked or linkable, the GWAS attack research means the specimen itself could someday be readily identifiable.<sup>64</sup> Because future use for research is anticipated at the time of collection for the biobank, applying the intent of the Common Rule means we should assume the sample itself would be readily identifiable in the future and effective counter measures may not exist.<sup>65</sup> This possibility of identification poses multiple risks to the individual, which parents should be able to assess and consent to, should they choose.<sup>66</sup> An additional point of controversy relates to the recommendation that consent does not pertain to research aimed at developing or improving NBS screening tests. Privacy advocates argue that screening test development or research conducted internally by the department of public health constitutes genetic research and thus falls under federal and state law.<sup>67</sup> In Minnesota, two ad-

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<sup>64</sup> See Homer et al., *supra* note 32, at 2; Jacobs et al., *supra* note 3233, at 1253, 1257; Catherine Heeney et al., *Assessing the Privacy Risks of Data Sharing in Genomics*, PUB. HEALTH GENOMICS (Mar. 29, 2010), at 2), <http://content.karger.com/produktedb/produkte.asp?doi=10.1159/000294150&typ=pdf> (discussing how data is identifiable, attack process, and risks related to disclosure); Stephanie Fullerton et al., *Meeting the Governance Challenges of Next-Generation Biorepository Research*, 2 SCI. TRANSLATIONAL MED. 1 (2010) (discussing why anonymization is insufficient for next-generation biobank sample sharing).

<sup>65</sup> See Jane Kaye et al., *Ethical Implications of the Use of the Whole Genome Methods in Medical Research*, 18 EUR. J. HUM. GENETICS 348 398, 398 (2010) (discussing how GWAS poses distinct challenges to preventing re-identification and effective countermeasures may be difficult to predict).

<sup>66</sup> See *id.* at 400; Jeantine E. Lunshof et al., *From Genetic Privacy to Open Consent*, 9 NATURE REV. GENETICS 406, 406-07 (2008) (discussing breaches of privacy and confidentiality resulting in stigma and discrimination).

<sup>67</sup> Press Release, Citizens' Council on Healthcare, Parent Consent for Storage and Use of Newborn DNA Should be Required (May 5, 2009), available at <http://www.cchconline.org/pr/pr051509.php>.

ministrative law judges have affirmed the latter position.<sup>68</sup>

The American College of Medical Genetics (ACMG) has classified the approximately 4.2 million NBS samples collected annually as a "valuable national resource."<sup>69</sup> If a state decides not to retain NBS samples for more than the screening test (often the only element to which parents consent, if the state uses a consent model), then ACMG recommends that individuals have the option to transfer their child's sample to a national NBS biobank.<sup>70</sup> Although this recommendation would increase the number of samples in a biobank and ensure their constructive use, it requires that parents know that their state department of health will retain and potentially share their child's NBS samples. However, it is unclear whether ACMG recommends consent, opt-out, or, at the very least, parental notification that the collected sample will be used for research following screening.<sup>71</sup> ACMG asserts that NBS are stored with "rigorous control and respect for privacy and confidentiality to protect the public."<sup>72</sup> Mentioning privacy rather than consent overlooks their distinct purposes and does not recognize that the Common Rule's requirements for consent may, and should, apply.<sup>73</sup>

Recognizing the value of NBS and that newborns possess an in-

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<sup>68</sup> In the Matter of the Proposed Amendments to Rules Governing Newborn Screening, Minnesota Rules, Chapter 4615, 11-0900-17586-1, ¶¶ 64, 67, available at <http://www.oah.state.mn.us/aljBase/090017586.rr.htm> (last visited April 8, 2011). Despite the ALJ's ruling, a recent ruling in the case *Bearder v. Minn.* dismissed plaintiffs' claims on the basis that Minnesota's Genetic Privacy Act does not apply to newborn blood samples or associated research using the samples. Order Granting Motion to Dismiss, *Bearder v. State*, No. 27-CV-09-5615, (Minn. Dist. Ct. Nov. 24, 2009), 2009 WL 5454446.

<sup>69</sup> *Position Statement on Importance of Residual Newborn Screening Dried Blood Spots*, AM. COLL. MED. GENETICS 2 (Apr. 29, 2009), [http://www.acmg.net/StaticContent/NewsReleases/Blood\\_Spot\\_Position\\_Statement2009.pdf](http://www.acmg.net/StaticContent/NewsReleases/Blood_Spot_Position_Statement2009.pdf).

<sup>70</sup> *Id.*

<sup>71</sup> *Id.* If state health departments do not even inform parents that their child's NBS will be used for research, then logically they cannot request that the state transfer the sample to a national biobank.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*; Mark A. Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J. L. MED. & ETHICS 89, 93 (2005) (discussing the distinct functions of consent and privacy in relation to the Common Rule and Privacy Rule).

terest related to it, the Newborn Screening Task Force (NSTF) of the Maternal and Child Health Bureau of the Health Resources Services Administration and the American Academy of Pediatrics recommended that each state develop and implement policies and procedures related to NBS.<sup>74</sup> NSTF noted that these policies should address the following elements: the objective of NBS storage, duration of storage, whether NBS will be stored with or without identifiers, and guidelines on the use of linked and unlinked samples.<sup>75</sup> Despite these detailed recommendations, many states have yet to develop comprehensive legislation or agency policy governing the collection, retention, and use of NBS.

## VI. STATE STATUTORY LAW RELATING TO NBS SAMPLES

### A. Overview of State Treatment and Terminology

Some states have taken steps to clarify the ambiguity of how to apply federal law relating to the disposition of NBS following the screening process.<sup>76</sup> State statutes vary on how NBS can or cannot be used and on whether samples collected for screening tests can be used subsequently for research purposes.<sup>77</sup> A 2006 study by Olney and colleagues, which reviewed forty-nine state policies, found approximately half stored NBS for more than six months.<sup>78</sup> Fifty-seven percent do not have written policies on how NBS can or cannot be used, and only sixteen percent informed parents that NBS might be retained.<sup>79</sup> A recent survey found fifteen state statutes contain lan-

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<sup>74</sup> Nanette Elster, *Future Uses of Residual Newborn Blood Spots: Legal and Ethical Considerations*, 45 JURIMETRICS J. 179, 182 (2005). In 1998, the Maternal and Child Health Bureau of the Health Resources Services Administration and the American Academy of Pediatrics convened the Newborn Screening Task Force to make recommendations on issues surrounding newborn screening. Michele A. Lloyd-Puryear et al., *American Academy of Pediatrics Newborn Screening Task Force Recommendations: How Far Have We Come?*, 117 PEDIATRICS S194, S195 (2006).

<sup>75</sup> Elster, *supra* note 74, at 182.

<sup>76</sup> *Id.* at 186.

<sup>77</sup> *Id.* at 186–87.

<sup>78</sup> Olney et al., *supra* note 2, at 619.

<sup>79</sup> *Id.* at 620.

guage regarding retention and research use of NBS.<sup>80</sup> Of these states, seven allow anonymous research without consent and three allow research on de-identified samples.<sup>81</sup>

These statistics suggest a discrepancy between the information provided to parents relating to the disposition of NBS and how NBS are used following the screening process. According to recent research, only twelve states provide information to parents pertaining to the use of NBS after screening is completed.<sup>82</sup> Merely four states notify parents that collected samples will be retained, explain privacy concerns, and provide parents a choice relating to disposition of samples.<sup>83</sup> If a majority of states do not have policies on how NBS can or cannot be used, but use the NBS for additional research, then most parents are not even aware that their child's sample is being used for additional research.<sup>84</sup> There is also a distinction between whether a health department discloses that it will retain the samples, use them for internal research, share them with its research partners, or whether research protocol are related to screening. For example, information brochures given to parents in Minnesota state that "[a]nonymous samples may be used to make sure the laboratory is doing a good job with testing or to develop new tests to screen for more disorders so even more babies can benefit from newborn screening."<sup>85</sup> The brochure itself does not inform parents that MDH intends to share the

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<sup>80</sup> Goldenberg, *supra* note 4, at 68. Goldenberg provides a chart with the fifteen states and information such as whether the state allows research with identifiable samples or de-identified samples, whether parents may opt-out of this research, and whether the state health department is tasked with educating parents on the retention of samples. *Id.* at 71.

<sup>81</sup> *Id.* at 68.

<sup>82</sup> *Id.* at 59. Goldenberg provides a chart with the fifteen states and information such as whether the state allows research with identifiable samples or de-identified samples, whether parents may opt-out of this research, and whether the state health department is tasked with educating parents on the retention of samples. *Id.* at 71. Goldenberg provides a table that explains what information each of the 12 states provides such as whether it discloses storage, but not research uses, discusses the issues of consent, or provides information on parental-opt-out of storage and use. Goldenberg, *supra* note 4, at 71.

<sup>83</sup> *Id.* at 59.

<sup>84</sup> *See id.* at 67, 70.

<sup>85</sup> MINN. DEPT. OF HEALTH, MINNESOTA NEWBORN SCREENING PROGRAM, ONE SIMPLE TEST CAN MAKE A DIFFERENCE FOR YOUR CHILD (2009), available at <http://www.health.state.mn.us/newbornscreening/docs/parentbrochureenglish.pdf>.



NBS with other entities (such as the Mayo Clinic, Perkin Elmer, or CDC) or that MDH will use the NBS to conduct research studies wholly unrelated to screening.<sup>86</sup>

Even if states do adopt language guiding the collection, retention, and research use of NBS, legislation relating to NBS must be individually interpreted as key terms may conflict from one state to another, or a state may provide a sweeping exemption to NBS banking and research. Some states classify NBS testing and/or banking research as genetic testing or research, and some do not.<sup>87</sup> Currently, seven states require consent to obtain access to genetic information, eight require consent to retain genetic information, and five define genetic information as personal property.<sup>88</sup> In addition to the information provided by statute, some state health departments contain additional policies at the agency level described in newborn screening parent brochures.<sup>89</sup>

## B. Squaring Newborn Screening and Additional Research with Genetic Privacy

Alaska is one state that contains two specific and relational statutes for newborn screening and genetic privacy.<sup>90</sup> Alaska requires consent to collect and perform analysis on an individual's DNA sample, but the statute clarifies that these consent requirements do not apply "to screen newborns."<sup>91</sup> By specifying this exception for newborn screening, this means the statute defines newborn screening as

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<sup>86</sup> *Id.* MDH's website now provides additional information on its research partners and projects. However, if the brochure does not allude to this information and parents do not visit MDH's website, parents who only read the brochure may not be fully informed. *Minnesota Newborn Screening Program, Use of Dried Blood Spots after Newborn Screening*, MINN. DEPT. OF HEALTH, <http://www.health.state.mn.us/newbornscreening/research.html> (last updated Sept. 21, 2010).

<sup>87</sup> Compare, e.g., ALASKA STAT. § 18.13.010 (2010), with MICH. COMP. LAWS ANN. §§ 333.17020, 333.17520 (West 2010).

<sup>88</sup> *Genetic Privacy Laws*, NAT'L CONF. OF STATE LEGISLATURES, <http://ncsl.org/default.aspx?tabid=14287> (last visited Nov. 12, 2010).

<sup>89</sup> Goldenberg, *supra* note 4, at 62.

<sup>90</sup> ALASKA STAT. § 18.13.010 (2010); ALASKA ADMIN. CODE tit. 7, §§ 27.510–27.530 (2010).

<sup>91</sup> ALASKA STAT. § 18.13.010 (2010).

the collection and analysis of a DNA sample.<sup>92</sup> Alaska also interprets the meaning of newborn screening according to the plain meaning of the term, describing the screening process as sample collection, screening, and reporting of results back to the newborn's parents.<sup>93</sup> This definition limits the use of the sample to actual screening rather than containing an implicit or generalized statement that screening includes unspecified retention or additional, possibly unrelated research following the screening.

To compare, other state statutes may not contain sections regarding consent to use samples for research, but the state health department can promulgate supplemental policies. Both Nebraska and Pennsylvania follow this model.<sup>94</sup> Their newborn screening statutes do not specify whether the health department must obtain consent prior to use of the NBS for research purposes, but their newborn screening parent brochures provide additional information.<sup>95</sup> A section in each brochure informs parents that the state department cannot use their child's NBS sample for research purposes without their consent.<sup>96</sup>

Unlike Alaska, Michigan contains specific protections for genetic information and genetic tests, but it also contains a broad exception for newborn screening and research. The genetic privacy portion of

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<sup>92</sup> *Id.*

<sup>93</sup> *Id.*; ALASKA ADMIN. CODE tit. 7, §§ 27.510–27.5.30; 27.897; 27.892–27.893 (2010) (discussing the compiling of health information for a public health purpose). Section 27.897 explicitly prohibits disseminating identifiable health information or medical records for a commercial purpose or any other purpose unrelated to its public health purpose. tit. 7, § 27.897. Section 27.893 states that the health department may disclose identifiable health information without patient consent in a narrow set of circumstances such as a public health agency as required by law, which, read in conjunction with the rest of this section, suggests it intends emergency circumstances rather than generalized research.

<sup>94</sup> NEB. REV. STAT. § 71-519 (2010); 35 PA. CONST. STAT. § 621–625 (2010).

<sup>95</sup> NEB. REV. STAT. § 71-519 (2010); 35 PA. CONST. STAT. § 621–625 (2010).

<sup>96</sup> Goldenberg, *supra* note 4, at 62; NEB. DEPT. OF HEALTH & HUMAN SERVS., NEBRASKA NEWBORN SCREENING PROGRAM, PARENT'S GUIDE TO YOUR BABY'S NEWBORN SCREENING (July 1, 2008), available at <http://www.dhhs.ne.gov/nsp/NewDocs/ParentsPage/Parents%20Guide%20July%202008.pdf>; PA. DEP'T. OF HEALTH, PENNSYLVANIA SCREENING SERVICES FOR NEWBORN BABIES (2009), available at <http://www.portal.state.pa.us/portal/server.pt?open=514&objID=558224&mode=2> (follow the "English" hyperlink).

the law requires that an individual consent to a genetic test, be informed of the future uses of the sample and information obtained from the sample, and be informed of who will have access to the sample following the test.<sup>97</sup> Despite this seemingly protective section, the law also states that “the term ‘genetic test’ does not include a procedure performed as a component of biomedical research” conducted pursuant to the Common Rule.<sup>98</sup> The section on newborn screening further carves out this exemption by stating that the informed consent requirements, which would normally require disclosure about the future use of the sample and who will have access to the sample, do not apply to newborn screening.<sup>99</sup> Despite this exception, the Michigan BioTrust implemented a system that utilizes a consent model based on feedback from focus groups and stakeholders during the development of the biobank.<sup>100</sup>

### C. Legislative Action to Address Statutory Uncertainty

Some states such as Minnesota and Texas exemplify the uncertainty and confusion of interpreting the newborn screening statute when determining whether genetic privacy protections apply or whether the statute permits or authorizes additional research. Spurred by litigation over these questions, both legislatures in Minnesota and Texas re-examined their screening statutes, arriving at very different outcomes.

Minnesota is one state that demonstrates the controversy of whether NBS are classified as genetic information and whether the state health department must obtain consent for banking and research use following screening. Prior to November 2009, a debate between privacy advocates and the Minnesota Department of Health

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<sup>97</sup> MICH. COMP. LAWS ANN. §§ 333.17020, 333.17520 (West 2010). Michigan’s statutory scheme specifically aligns with its BioTrust bank of NBS using an opt-out model for research. *See* Goldenberg, *supra* note 4, at 87. A discussion of the legal and ethical differences of a consent versus an opt-out model for research using NBS is outside the scope of this article.

<sup>98</sup> MICH. COMP. LAWS ANN. §§ 333.17020, 333.17520 (West 2010).

<sup>99</sup> MICH. COMP. LAWS ANN. § 333.5431 (West 2010).

<sup>100</sup> Email from Janice Bach, MS, CGC, State Genetics Coordinator and Manager, Genomics and Genetic Disorders Section Michigan Dep’t of Community Health, to author (May 28, 2010, 18:54 CST) (on file with author).

(MDH) arose, centered around whether the newborn screening program activities (inclusive of subsequent research and sharing of NBS) were exempt from the Minnesota Genetic Privacy Act (GPA).<sup>101</sup> Minnesota defines genetic information as information about an identifiable individual derived from either the specimen itself or biological information.<sup>102</sup> The GPA specifies that consent is required to collect genetic information and that the information may only be used for the purposes to which the individual has given consent, may only be stored for the period for which the individual has given consent, and may only be disseminated with the individual's consent.<sup>103</sup> During a rulemaking session, a Minnesota Administrative Law Judge found that the GPA did apply to the newborn screening and research activities; thus, MDH was required to amend the rule so it would obtain parents' consent to retain and use NBS for research, even for internal research in the department to obtain ALJ approval.<sup>104</sup> Despite this conclusion and insistence from privacy advocates, MDH declined to adopt this finding and continued to collect, retain, and use NBS for research purposes without express consent.<sup>105</sup>

Beginning in 2008, legislators introduced H.R. 1341, S.F. 3138 and S.F. 1478 as a means to exempt newborn screening from the GPA.<sup>106</sup>

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<sup>101</sup> See Complaint of Plaintiff at 2, *Bearder v. State*, No. 27-CV-09-5615 (Minn. Dist. Ct. Mar. 11, 2009), 2009 WL 4893192 [hereinafter *Bearder Complaint*].

<sup>102</sup> MINN. STAT. § 13.386 (2009).

<sup>103</sup> *Id.*

<sup>104</sup> In the Matter of the Proposed Amendments to Rules Governing Newborn Screening, *supra* note 68, at ¶ 67. Prior to November 2009, the Minnesota Department of Health maintained that the Genetic Privacy Act did not apply to its practices relating to retaining and using NBS and did not obtain informed consent for additional retention and research use. Mark McCann, Manager of Public Health Laboratory in the Newborn Screening Program testified before the Minnesota Senate that "the number of parents who have given consent to store . . . residual dried blood spots with the Minnesota Department of Health is zero" and, according to McCann, actually obtaining consent is not a current practice. See Plaintiffs' Memorandum of Law, *Bearder v. State*, No. 27-CV-09-5615 (Minn. Dist. Ct. Oct. 1, 2009), 2009 WL 5427609 at \*16.

<sup>105</sup> Plaintiffs' Memorandum of Law, *supra* note 104, at \*14; In the Matter of the Proposed Amendments to Rules Governing Newborn Screening, *supra* note 68, at ¶ 67. The ALJ's decision was not binding on MDH to require it to adopt the rule she suggested, but it would require the MDH to amend the proposed rule per the ALJ's instructions if it wanted to adopt the originally proposed rule.

<sup>106</sup> H.R. 1341, 86th Leg. (Minn. 2009); S.F. 3138, 85th Leg. (Minn. 2008); S.F. 1478, 86th Leg.

Minnesota Governor Tim Pawlenty vetoed S.F. 3138, cited the ALJ's opinion, confirmed that retention and use of NBS fell under the GPA, and expressed vehement concern that MDH would circumvent obtaining consent for long term retention and unrelated research.<sup>107</sup> Both the proposed legislative action and the veto demonstrate that, as the newborn screening statute previously existed, it was not exempt from the GPA. In November 2009, a Minnesota district court judge ruled to the contrary, finding that the GPA did not apply to the newborn screening statute and its associated programs.<sup>108</sup> The appellate court in Minnesota affirmed this finding in August 2010.<sup>109</sup> This lengthy battle demonstrates that even when a state may appear to clarify protections for newborns and require parental consent, the state department of health may argue those requirements are not applicable to its activities and a court may later interpret the law in support of this conclusion.

Prior to May 2009, Texas also had conflicting legislation relating to newborn screening and genetic privacy.<sup>110</sup> Despite this ambiguity,

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(Minn. 2009).

<sup>107</sup> Letter from Minnesota Governor Tim Pawlenty, Minnesota Governor, to James Metzen, President of the Minnesota Senate (May 20, 2008), available at [http://www.forhealthfreedom.org/BackgroundResearchData/MN\\_NewbornScreening2008.pdf](http://www.forhealthfreedom.org/BackgroundResearchData/MN_NewbornScreening2008.pdf). In the letter, Gov. Pawlenty explains his veto of S.F. 3138: "I understand the [Minnesota Department of Health's] desire to collect and use blood samples for newborn screening purposes using an opt-out approach. However, I believe written informed consent should be obtained for long-term storage or use of the blood samples for non-screening research. Government handling and storage of genetic information is a serious matter. Removing the requirement for express authorization from parents regarding the long term storage and potential future uses of genetic samples, especially when such storage and use is not related to newborn screening, is concerning." *Id.* (emphasis added).

<sup>108</sup> Order Dismissing Plaintiffs' Complaint, *Bearder v. State*, No. 27-CV-09-5615 (Minn. Dist. Ct. Nov. 24, 2009), 2009 WL 5454446, available at <http://bioethics.iu.edu/programs/predicter/legal-updates/newborn-blood-spot-banking/>.

<sup>109</sup> *Bearder v. Minn.*, 788 N.W.2d 144, 152 (Minn. Ct. App. Nov. 24, 2009).

<sup>110</sup> TEX. HEALTH & SAFETY CODE ANN. § 33.012 (Vernon 2005); TEX. OCC. CODE ANN. § 58.103 (Vernon 2005). Section 58.103 states that genetic information may be disclosed without an authorization if the disclosure is for a research study in which the procedure for obtaining consent conforms to the Common Rule, the information does not identify a specific individual, and the information is provided to the Department of Health to comply with a separate section of the Texas Health and Safety Code. This section suggests that obtaining genetic information requires consent and that disclosure of genetic information is restricted to these particular circumstances.

the Texas Department of State Health Services (TDSHS) collected, retained, and used NBS without consent for use beyond screening.<sup>111</sup> In May 2009, Texas Governor Rick Perry signed H.B. 1672 into law, which outlined an opt-out policy for retention and use of NBS.<sup>112</sup> The new law, which took effect in May 2009, required TDSHS to develop a disclosure statement distributed to parents, explaining that the NBS will be retained by TDSHS and informing parents of the option to submit a written request to destroy the NBS to prevent retention.<sup>113</sup> The statute does not mandate that the disclosure statement include information about particular research use of the NBS within TDSHS or associated research entities, which opponents argued is not full disclosure.<sup>114</sup> Additionally, a portion of the statute allows the NBS samples to be released for research purposes without consent if the research has been approved by an IRB or privacy board.<sup>115</sup>

## VII. PUBLIC ATTITUDES TOWARD COLLECTION FOR RETENTION AND RESEARCH USING NBS WITHOUT CONSENT

Recent research suggests a troubling discrepancy between current practices in some states that do not obtain consent and public attitudes showing the importance of consent.<sup>116</sup> In 2009, Tarini and colleagues published a study that examined parental willingness to permit NBS sample storage and research without their consent.<sup>117</sup> If permission is obtained, 76.2% of parents were very or somewhat willing to permit use of NBS for research.<sup>118</sup> If permission was not obtained, only 28.2% of parents would be very or somewhat willing to

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<sup>111</sup> Plaintiff's Complaint, *Beleno v. Tex. Dep't of State Health Servs.* at 3–4, No. SA-09-CA-188-FB (W.D. Tex. Mar. 12, 2009), 2009 WL 5072234 at 3–4 [hereinafter *Beleno Complaint*].

<sup>112</sup> H.B. 1672, 81<sup>st</sup> Leg., Reg. Sess. at 2 (Tex. 2009).

<sup>113</sup> TEX. HEALTH & SAFETY CODE ANN. § 33.0111 (Vernon 2009).

<sup>114</sup> See Ken Ortolon, *Blood Feud: Controversy Arises Over Newborn Screening Program*, TEX. MED., July 2009, at 47, 49.

<sup>115</sup> TEX. HEALTH & SAFETY CODE ANN. § 33.017(b)(5) (Vernon 2009).

<sup>116</sup> Beth A. Tarini et al., *Not Without My Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research*, PUB. HEALTH GENOMICS, July 11, 2009, at 1, 5.

<sup>117</sup> *Id.* at 1–2.

<sup>118</sup> *Id.* at 1.

permit use of NBS for research.<sup>119</sup> These figures suggest that parents want to be informed and be asked for consent to provide NBS. Notably, this research also suggests that parents *would* consent to allow retention and research use of their child's NBS sample following screening, provided they were asked. These results undermine the assumption that researchers must circumvent consent to collect samples for a robust research agenda.

Following the passage of HB 1672, which implemented the inform and opt-out system in Texas, parents have responded to the change in the law.<sup>120</sup> Now that TDSHS is required to inform parents that it will retain and use NBS, between the implementation in September 2009 to November 2009, 8200 parents chose to opt-out of retention for research and requested that TDSHS destroy their child's NBS following screening use.<sup>121</sup> Both the number of parents responding and the immediacy of their action suggest that parents both want and will use the option not to involve their child in research.

Failing to address and remedy this disconnect between health department practices and parental attitudes could have several negative unintended consequences for all parties involved. If a state legislature or health department does not inform parents and obtain consent, parents may opt-out of newborn screening altogether using a statutory exemption, which would be detrimental and potentially pose health consequences for the newborn.<sup>122</sup> Overlooking the autonomy and dignity of parents acting as guardians for their newborns could cause parents to lose trust in biobanking research, which would hinder future collection efforts.<sup>123</sup> Additionally, parents could turn to the judicial system for private remedy if they feel that neither the state health department nor the state legislature respects their

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<sup>119</sup> *Id.*

<sup>120</sup> See Nanci Wilson, *Government Taking Newborn DNA Samples: Many Ask Why They Are Saving the Samples*, AUSTIN NEWS KXAN, (Nov. 23, 2009), <http://www.kxan.com/dpp/health/government-taking-newborn-dna-samples> (last updated Nov. 24, 2009).

<sup>121</sup> *Id.*

<sup>122</sup> Goldenberg, *supra* note 4, at 82-83.

<sup>123</sup> Charles Thomas, *The Use and Control of Heel Prick Blood Samples*, 24 MED. & L. 259, 277 (2005).

rights to act as guardians of potential research subjects.<sup>124</sup> In December 2009, a litigation settlement in Texas prescribing the destruction of 4.2 million samples<sup>125</sup> demonstrated that private remedy may indeed have significant deleterious impact on research endeavors.<sup>126</sup>

### VIII. MINNESOTA AND TEXAS: CONTRASTING OUTCOMES CLARIFYING CONSENT<sup>127</sup>

In 2009, courts in both Minnesota and Texas examined the issue of whether the state health department may retain and use samples following screening use without parental consent.<sup>128</sup> In both cases, parents filed suit on behalf of their newborn children and initiated claims against the state health department, alleging their failure to obtain consent for NBS storage and research constituted a number of legal violations.<sup>129</sup> As discussed in the following pages, both states contained vastly different statutory requirements on the issue and each case reached a non-intuitive resolution. The following examples demonstrate the vast disconnect between individual legal interests related to NBS samples and state health department assumptions governing their collection and use protocol.

#### A. *Bearder v. Minn.*

In June 2009, seventeen Minnesota parents (collectively referred to as either *Bearder, et al.* or Plaintiffs) filed a civil complaint against the State of Minnesota, the Minnesota Department of Health (MDH), and its Commissioner, Sanne Magnan (collectively Defendants), alleging a series of claims, including violation of the Minnesota Genetic

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<sup>124</sup> See Wilson, *supra* note 120, for examples of such litigation.

<sup>125</sup> Beleno Complaint, *supra* note 111.

<sup>126</sup> Settlement Agreement and Release at 3, *Beleno v. Tex. Dept. of State Health Servs.*, No. SA-09-CA-188-FB (W.D. Tex., Dec. 22, 2009) [hereinafter Settlement Agreement].

<sup>127</sup> This article provides more substantive discussion regarding *Beleno* than *Bearder* based on the amount of resources available. At the time of this research, filings were only available through party attorneys and I relied on email requests for copies of each document. Attorneys in the *Beleno* case provided more court filings, so the discussion is allotted accordingly.

<sup>128</sup> See *Bearder Complaint*, *supra* note 101; See *Beleno Complaint*, *supra* note 111.

<sup>129</sup> See *Bearder Complaint*, *supra* note 101; See *Beleno Complaint*, *supra* note 111



Privacy Act (GPA), eight tort claims, fundamental right claims, and government taking.<sup>130</sup> Plaintiffs maintained that the Minnesota GPA governed MDH's actions because NBS constitute genetic information under the GPA and the newborn screening statute did not contain an express provision that would exempt MDH's retention of NBS for research from the GPA's consent requirements.<sup>131</sup> Plaintiffs argued that Minnesota's use of an opt-out system was not sufficient to comply with the GPA's requirement for explicit consent.<sup>132</sup> Even without the GPA's express provisions, Bearder et al. argued that a person has a privacy interest in his or her own blood (acting as guardian for the newborn's blood) and the medical information that may be obtained from it based on its deeply personal nature.<sup>133</sup> Plaintiffs' Memorandum of Law also expounded on the important distinction between screening and research.<sup>134</sup> Plaintiffs maintained that the newborn screening statute only conferred authority to MDH for screening while the GPA was designed to cover the disposition of the samples following said screening.<sup>135</sup> Thus, plaintiffs concluded that due to

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<sup>130</sup> Bearder Complaint, *supra* note 101, at 2–3. Both parties also raise the issues of sovereign and qualified immunity. Plaintiffs argued defendants were not immune from liability for violation of the GPA because the GPA explicitly waives the state's immunity. Plaintiff's Memorandum of Law, *supra* note 104, at 36. Plaintiffs also argued against qualified immunity based on the assertion that MDH Commissioner's action violated Constitutional privacy principles. *Id.* at 56–57. Defendants asserted that plaintiffs' claims were in fact barred by sovereign immunity and qualified immunity because the Commissioner acted within her official duties and did not violate any clearly established rights under the Constitution. Defendants' Supplemental Memorandum in Support of Motion to Dismiss First Amended Complaint or, in the Alternative, Summary Judgment, *Bearder v. State*, No. 27-CV-09-5615 (Minn. Dist. Ct. Aug. 18, 2009) 2009 WL 5427610 at 12. However, Defendants' Supplemental Memorandum acknowledges that courts are split on whether the privacy of medical information is protected, which would implicate a Constitutional privacy violation and eliminate qualified immunity. *Id.* at 13–14. Judge Rosenbaum's order merely accepted Defendants' conclusion that immunity existed, which effectively, and problematically, disposed of Plaintiffs' tort and Constitutional claims without discussion. See Order Granting Motion to Dismiss, *supra* note 68.

<sup>131</sup> Plaintiff's Memorandum of Law, *supra* note 104, at 32. Plaintiffs used a dictionary definition of information to show that the DNA in the sample constitutes genetic information, so the NBS should be classified as genetic information under the GPA. *Id.* at 23–24.

<sup>132</sup> See *id.* at 31.

<sup>133</sup> *Id.* at 49–50.

<sup>134</sup> See *id.* at 27, 30.

<sup>135</sup> Plaintiff's Memorandum of Law, *supra* note 104, at 28, 31.

MDH's continued retention and use of the NBS without explicit consent, MDH exceeded the scope of its authority under screening statutes and was accordingly noncompliant with the GPA as well as in violation of the newborns' privacy and property interests.<sup>136</sup> Under a claim for fraud and misrepresentation, Bearder et al. also contended that MDH intentionally omitted the fact that the NBS were not taken solely for screening but would be retained and used, that MDH knew parents would provide them NBS for the purpose of screening, and that parents relied on these representations but would not have consented to providing NBS for research had they known.<sup>137</sup> In their Prayer for Relief, Plaintiffs requested damages as statutorily indicated, an injunction, and an order against MDH compelling compliance.<sup>138</sup>

Defendants answered by arguing the GPA did not apply to MDH's actions and MDH did not disseminate any of Plaintiffs' genetic information when deciding to retain and use the NBS for research.<sup>139</sup> Defendants filed a Motion to Dismiss, or in the alternative, Summary Judgment in their favor and set forth a Memorandum of Law to counter Plaintiffs' arguments.<sup>140</sup> Defendants' position rested on the proposition that the GPA did not apply to the newborn screening program.<sup>141</sup> First, Defendants argued NBS do not fall within the definition of genetic information.<sup>142</sup> To support their position, Defendants relied on the argument that the legislature did not intend to include a blood sample within the definition of genetic information.<sup>143</sup> However, Plaintiffs' Memorandum of Law also provided additional

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<sup>136</sup> *Id.* at 31, 53-56.

<sup>137</sup> First Amended Complaint, Bearder v. State, No. 27-CV-09-5615 (Minn. Dist. Ct. June 30, 2009) 2009 WL 5427622.

<sup>138</sup> Bearder Complaint, *supra* note 101, at 4.

<sup>139</sup> Order Dismissing Plaintiff's Complaint, *supra* note 108, at 7.

<sup>140</sup> Defendants' Memorandum in Support of Motion to Dismiss, or in the Alternative, Motion for Summary Judgment on Plaintiffs' State Statutory Claim, Bearder v. State, No. 27-CV-09-5615 (Minn. Dist. Ct. Aug. 18, 2009).

<sup>141</sup> Order Dismissing Plaintiff's Complaint, *supra* note 108, at 7.

<sup>142</sup> Defendants' Memorandum in Support of Motion to Dismiss, or in the Alternative, Motion for Summary Judgment on Plaintiffs' State Statutory Claim, *supra* note 140.

<sup>143</sup> *Id.* at 22.

discussion of the GPA's legislative history, contradicting Defendant's position by showing the GPA was meant to apply to NBS collection, retention, and use.<sup>144</sup> Additionally, these legislative sessions discussed that MDH should have been obtaining consent to retain the samples and, absent consent, destroying them within a period after screening.<sup>145</sup>

Second, Defendants asserted that the newborn screening statute's provision stating samples "may be retained" by the MDH constitutes an express provision exempting MDH from the GPA's usual requirement of consent to retain, use, or share genetic information for research.<sup>146</sup> Based on this interpretation, Defendants countered Plaintiffs' privacy and tort claims by asserting they lawfully acquired and possessed the NBS as statutorily proscribed, undermining any impermissible intrusion into Plaintiffs' rights.<sup>147</sup>

However, as Plaintiffs noted, Defendants' interpretation of the newborn screening statute problematically conflated screening and research.<sup>148</sup> MDH not only used NBS to analyze the presence, absence, or mutation of a disease to obtain medical and biological information, but both internally used and disseminated the samples to private entities for other health studies.<sup>149</sup> Plaintiffs clarified the new-

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<sup>144</sup> Plaintiffs' Memorandum of Law, *Bearder*, *supra* note 104, at 15-17.

<sup>145</sup> *Id.* (citing to multiple legislative hearings). At a March 16, 2009 hearing Minnesota State Senator David Hann confronted Mark McCann of MDH regarding the issue of consent. Senator Hann stated he thought the law required parents to provide consent for the MDH to collect and store their children's genetic material. Specifically, Senator Hann said he did not understand why the MDH did not change its rule to incorporate consent after the Administrative Law Judge found MDH's policy, that which did not include a consent provision, constituted a defect. McCann replied it was not MDH's current practice to obtain consent and zero parents have actually provided consent. Further, at a March 17, 2009 committee session, Minnesota House of Representatives members Tom Emmer and Paul Thissen explained their belief that under the GPA the MDH should have been destroying the NBS. *Id.* at 17.

<sup>146</sup> Defendants' Memorandum in Support of Motion to Dismiss, or in the Alternative, Motion for Summary Judgment on Plaintiffs' State Statutory Claim, *supra* note 140, at 18-21.

<sup>147</sup> *Id.* at 3, 9, 16. Defendants also argued that MDH and Commissioner acted within official statutory duties and exercised reasonable discretion, which would bar Plaintiffs' claims based on sovereign and qualified immunity. *Id.* at 20-23.

<sup>148</sup> Plaintiffs' Memorandum of Law, *supra* note 104, at 28.

<sup>149</sup> Order Dismissing Plaintiff's Complaint, *supra* note 108, at 3; Plaintiff's Memorandum of Law, *supra* note 104, at 31.

born screening statute only provided MDH authority to collect and use NBS for screening, but did not confer it authority for additional retention or to share the NBS with outside entities for research purposes.<sup>150</sup>

In November 2009, Judge Marilyn Rosenbaum handed down an order granting Defendants' Motion to Dismiss all claims in the entirety.<sup>151</sup> Judge Rosenbaum wholly accepted Defendants' argument relating to statutory interpretation of the GPA, which in turn defeated Plaintiffs' additional tort and fundamental right claims.<sup>152</sup> Despite contradictions and uncertainty in legislative history relating to the GPA, Judge Rosenbaum summarily rejected Plaintiffs' supporting information and concluded the newborn screening program and research using NBS did not fall within the requirements of the GPA.<sup>153</sup> Furthermore, "[e]ven if the GPA would apply, Judge Rosenbaum concluded that the statutory provision stating that NBS 'may be retained by [MDH]' constituted an express provision that would exempt MDH's retention, research use, and research sharing from the GPA."<sup>154</sup> Thus, Judge Rosenbaum's conclusion that the GPA did not apply to MDH's treatment of the NBS following screening meant that the MDH's research activities were within its discretion and did not violate Plaintiffs' rights. As a result, Judge Rosenbaum ruled that Plaintiffs had no viable claims and dismissed Plaintiffs' complaint in

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<sup>150</sup> Plaintiffs' Memorandum of Law, *supra* note 104, at 28 (stating that "nothing in the newborn screening statutes permits Defendants to store test results and samples indefinitely, use the test results and samples for anything other than newborn screening, or disseminate the test results to private entities for public and private health studies").

<sup>151</sup> Order Dismissing Plaintiff's Complaint, *supra* note 108, at 11.

<sup>152</sup> *Id.* at 10 (stating that "[t]he blood samples taken pursuant to the NBS Program are biological samples, not genetic information as defined in the GPA").

<sup>153</sup> *See id.* Judge Rosenbaum glossed over the contradictory legislative testimony provided by both parties and merely accepted Defendants' portion of the testimony. Plaintiffs' discussion of legislative testimony illustrated that members of the Minnesota House and Senate believed that the GPA applied to collection and use of NBS outside of screening itself, yet because MDH did not believe so, it acted accordingly. Plaintiff's Memorandum of Law, *supra* note 104, at 15–17. Thus, Plaintiffs sought judicial remedy to clarify the law when legislative session could not. Yet Judge Rosenbaum later ironically states that the court cannot impose the remedy plaintiffs seek and they should "press their concerns to the legislature." Order Dismissing Plaintiff's Complaint, *supra* note 108, at 10.

<sup>154</sup> *Id.*

its entirety.<sup>155</sup>

Judge Rosenbaum's order demonstrates that despite an additional genetic privacy law that seemingly required consent to retain and use NBS for research, a court's interpretation of two statutory sections can be highly unpredictable. By concluding that the GPA did not apply to the newborn screening program, the court is in effect saying there is no need for MDH to obtain consent to retain and use NBS for research.<sup>156</sup> Further, in holding Defendants lawfully acquired and used the NBS, the court's order also ratifies the blurred distinction between screening and research. In August 2010, the appellate court affirmed this dismissal of Plaintiffs' claims. Both of these findings set a problematic precedent for both parents and potential plaintiffs in other jurisdictions who may seek recognition that NBS retention and research requires consent.

#### **B. *Beleno v. Tex. Dept. of State Health Servs.***

Unlike Minnesota, where the court dismissed the Plaintiffs' claims, the Texas court denied defendants' Motion to Dismiss, which resulted in the parties eventually reaching a settlement.<sup>157</sup> Legal action began in March 2009 when parents, Beleno, et al. (also referred to as Plaintiffs), filed a civil complaint against the Texas Department of State Health Services (TDSHS) and other defendants similarly claiming TDSHS had no legal authority to retain and use the NBS without consent.<sup>158</sup> Among a litany of claims, Beleno, et al. asserted this practice violated privacy principles stemming from the Fourth and Fourteenth Amendments to the United States Constitution and state privacy laws, as well as violated a prohibition against seizure.<sup>159</sup> In their Prayer for Relief, Beleno, et al. requested that the court order either the destruction of all NBS stored without consent (around four mil-

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<sup>155</sup> *Id.* at 11.

<sup>156</sup> MDH uses an opt-out policy where parents can submit a destruction request to destroy their child's sample. MINN. STAT. § 144.125 subd. 3 (2010). However, a barrier to exercising the opt-out policy may be created if parents are not informed, or not fully informed, on how the NBS will be used after screening.

<sup>157</sup> Settlement Agreement, *supra* note 126.

<sup>158</sup> Beleno Complaint, *supra* note 111, at 4.

<sup>159</sup> *Id.* at 5-6.

lion samples) or obtain retroactive parental consent.<sup>160</sup> Additionally, Plaintiffs sought an order to compel TDSHS to disclose for what purposes the NBS had been used and financial transactions involving the NBS.<sup>161</sup>

Defendants answered by arguing that, because consent was not required to collect samples for retention and research, their procedures comported with the law;<sup>162</sup> filed a Motion to Dismiss;<sup>163</sup> and separately filed Answers with Affirmative Defenses.<sup>164</sup> Defendants argued the Common Rule did not apply,<sup>165</sup> a privacy interest did not exist (or, in the alternative, existing law adequately protected this interest),<sup>166</sup> Plaintiffs' consent for NBS collection for screening negated subsequent claims,<sup>167</sup> and TDSHS acted in the public interest.<sup>168</sup> Both the Motion to Dismiss as well as the Answers addressing these topics contained several logically problematic assertions that undermined Defendants' denials and refutation.

First, Defendants argued they acted in accordance with the law because the Common Rule's consent requirements did not apply to NBS that were collected and subsequently de-identified.<sup>169</sup> This assertion could potentially contain two problems. The first problem is that Defendants may assume that screening validation or internal devel-

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<sup>160</sup> *Id.* at 6, 8–9; *See Ortolon, supra* note 114, at 49.

<sup>161</sup> Beleno Complaint, *supra* note 111, at 9.

<sup>162</sup> Defendant Texas A&M's Motion to Dismiss Plaintiffs' Original Complaint, *Beleno v. Tex. Dep't of State Health Servs.*, No. SA09CA188FB, (W.D. Tex. May 29, 2009) 2009 WL 5072237 at 17–19 (citing 45 C.F.R. § 46.101(b)(4) (2009)).

<sup>163</sup> *Id.*

<sup>164</sup> Defendant Texas A&M's Original Answer and Affirmative Defenses to Plaintiffs' Original Complaint, *Beleno v. Tex. Dep't of State Health Servs.*, No. SA09CA188FB, (W.D. Tex. May 18, 2009).

<sup>165</sup> Defendant Texas A&M's Motion to Dismiss Plaintiffs' Original Complaint, *supra* note 162, at 12–14 (discussing the Common Rule and consent).

<sup>166</sup> *Id.* at 8–10 (discussing privacy).

<sup>167</sup> Defendant Texas A&M's Original Answer and Affirmative Defenses to Plaintiffs' Original Complaint, *supra* note 162, at 10 (discussing plaintiffs' consent to screening as an affirmative defense).

<sup>168</sup> *Id.* at 5 (discussing how defendants acted in the public interest).

<sup>169</sup> Defendant Texas A&M's Motion to Dismiss Plaintiffs' Original Complaint, *supra* note 162, at 110 & n.8.

opment research conducted within the health department does not constitute research under the Common Rule.<sup>170</sup> The second problem is that Defendants' Answer is unclear as to the timing of the de-identification process — whether TDSHS de-identified the samples immediately upon receipt, following some internal research, or prior to transferring them to Texas A&M Health Sciences Center School of Rural Public Health (TAMU).<sup>171</sup> This distinction is important because the applicability of the Common Rule looks to the purpose of collection and identifiability to the investigator.<sup>172</sup>

In response to Plaintiffs' privacy concerns, Defendants provided two potential arguments. Defendants admitted that the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations apply, but denied that Plaintiffs possessed a privacy interest over the NBS, or, in the alternative, that existing law did not adequately protect Plaintiffs' privacy interests.<sup>173</sup> Defendants' Motion to Dismiss asserted that storage of NBS failed to fall within a recognized zone of privacy, Defendants' actions had "no effect whatsoever" on Plaintiffs, and no conceivable privacy interest existed.<sup>174</sup> TDSHS's laboratory that performs the NBS tests is covered under HIPAA and both TDSHS and TAMU used their own IRB to review potential research projects using the samples to ensure the protection of newborns' privacy rights.<sup>175</sup> HIPAA coverage means the law recognized that the sensitive, personal nature of NBS implicates legal privacy protections and IRB review served as the means to ensure that those privacy in-

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<sup>170</sup> Defendants' Answer does not clarify whether they classify this category of research as "research" that would activate the applicability of the Common Rule. See Defendant Texas A&M's Original Answer and Affirmative Defenses to Plaintiffs' Original Complaint, *supra* note 164, at 4, 6.

<sup>171</sup> After receiving the samples, TDSHS transferred them to Texas A&M Health Sciences Center School of Rural Public Health, where they were stored, processed for subsequent retrieval, and transferred back to TDSHS for additional research. See Beleno Complaint, *supra* note 111, at 3–4. See also Pelias & Markward, *supra* note 25, at 182–83 (discussing generally if and when state health departments de-identify samples).

<sup>172</sup> Drabiak-Syed, *supra* note 20, at 300.

<sup>173</sup> Defendant Texas A&M's Motion to Dismiss Plaintiffs' Original Complaint, *supra* note 162, at 19–21.

<sup>174</sup> *Id.* at 9–10.

<sup>175</sup> *Id.* at 15, 18–20.

terests were being adequately protected. The applicability of HIPAA and IRB review demonstrated the Defendants' activities operated within a zone of privacy.

As in *Bearder*, Defendants' responses relating to Common Rule applicability as well as their affirmative defense that Plaintiffs consented to providing the NBS blurred the distinction between screening and subsequent retention and or research.<sup>176</sup> As discussed above, parents may have consented to allowing their infant's blood to be taken for newborn screening tests, but they did not provide consent to allow TDSHS to retain their infant's NBS for research.<sup>177</sup> Defendants erroneously broadened the scope of consent when they argued that parental consent to screening undermined Plaintiffs' claims.<sup>178</sup> Defendants asserted they were legally justified in their actions even though the samples were originally collected for screening purposes.<sup>179</sup> Further, while Defendants' Answer maintained that the NBS were not used in a manner unrelated to the purpose for which the samples were originally drawn, it admitted the NBS were used for cancer research that was not directly related to determining whether a newborn is born with a genetic or metabolic condition.<sup>180</sup>

Defendants' Response maintained that Defendants acted only in the interest of the public, which distorted an important distinction. Defendants misapplied the converse of Plaintiffs' contention that consent should be overridden only where a compelling public health issue exists which is sufficient to overcome an intrusion into one's privacy.<sup>181</sup> Acting in the interest of the public does not equate to action arising from a compelling public health reason. Regardless, even if Defendants were acting in the interest of the public, this does not negate the requirement for informed consent.<sup>182</sup>

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<sup>176</sup> *Id.* at 8–10.

<sup>177</sup> *Id.* at 8–9.

<sup>178</sup> See Original Answer and Affirmative Defenses to Plaintiffs' Original Complaint, *supra* note 164, at 10.

<sup>179</sup> *Id.* at 4–5.

<sup>180</sup> See *id.* at 4, 6.

<sup>181</sup> *Id.* at 5.

<sup>182</sup> See *infra* text accompanying notes 211–216 (discussing the shortcomings of the United Kingdom's General Medical Council's recommendations to forgo obtaining consent or over-



In response, Plaintiffs further explained why retaining NBS absent consent constituted a privacy violation and a viable injury.<sup>183</sup> Plaintiffs' Response to Defendants' Motion to Dismiss Plaintiffs' Original Complaint attempted to clarify their belief that TDSHS had only narrow statutory authority to collect and use NBS for screening purposes; thus additional retention and use was outside the scope of its authority and violated constitutional prohibitions against seizure.<sup>184</sup> Importantly, Plaintiffs also clarified the distinct function of consent with a constitutional privacy and seizure analysis.<sup>185</sup> Plaintiffs argued that even if samples were later de-identified, this did not remedy the defect of failing to obtain consent initially.<sup>186</sup> Plaintiffs' Response also noted that because NBS contain deeply private medical and genetic information, passive storage alone implicates a privacy interest and constitutes a per se legal violation.<sup>187</sup> Plaintiffs' arguments and responses set forth the proposition that collection for retention and research is governed by human subjects research guidelines, and that failure to comply with the requirement for consent not only violates the Common Rule, but implicates constitutional privacy concerns because the Defendants' acted outside their scope of authority.

In September 2009, U.S. District Court Judge Fred Biery denied Defendants' Motions to Dismiss.<sup>188</sup> In December 2009, the parties

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ride a consent refusal to use personal information for important medical research).

<sup>183</sup> Plaintiffs' Response to Defendants' Motion to Dismiss Plaintiffs' Original Complaint, *Beleno v. Tex. Dept. of State Health Servs.*, No. SA09CA188FB, (W.D. Tex. June 9, 2009) 2009 WL 5072234.

<sup>184</sup> *Id.* at 9.

<sup>185</sup> *Id.* at 10-13.

<sup>186</sup> *Id.* at 10.

<sup>187</sup> *Id.* at 7, 10-11. Plaintiffs' Response aptly compares passive storage of genetic information to the following: "If a gentleman provides a semen sample for fertility testing and it is further stored, without his consent, at another location for a future undisclosed purpose, certainly the fact that this storage is passive . . . is irrelevant." Plaintiffs' Response to Defendants' Motion to Dismiss Plaintiffs' Original Complaint, *supra* note 183, at 10. The example demonstrates that obtaining and possessing deeply private personal information without consent even absent additional action constitutes an injury per se.

<sup>188</sup> Press Release, Texas Civil Rights Project, Judge Refuses to Dismiss TCRP Lawsuit on Secretive Collecting and Storing Newborn Blood Samples (Sept. 21, 2009), available at <http://www.texascivilrightsproject.org/?p=1608> (last visited December 14, 2009).

reached and filed a Settlement Agreement that adopted several elements of Plaintiffs' Prayer for Relief relating to the program operation practices as well actions applicable to the specific plaintiffs.<sup>189</sup> The Settlement Agreement provided that TDSHS would destroy the approximately 4.5 million samples taken between 2002 (when it began retaining samples for research) and May 27, 2009.<sup>190</sup> It also proscribed two general informational requirements: TDSHS must post on its website (1) a list of all research projects for which it has provided samples and (2) a list of categories of quality assurance and quality control use projects for which it has provided samples as of the settlement date.<sup>191</sup> Additionally, TDSHS must inform Plaintiffs in writing of how their child's sample was used and any financial transactions involving that sample.<sup>192</sup>

Both the change in Texas law and the Settlement Agreement establish several important points. First, Texas' implementation of the opt-out model recognizes that retention and research are distinct from screening.<sup>193</sup> Second, both the current law and the Settlement Agreement emphasize that parents should be informed and able to assert a preference for exclusion of their child's sample following screening.<sup>194</sup> Third, the posting of the above noted information on TDSHS's website under the dictates of the Settlement Agreement further demonstrates the importance of parents having information relating to the disposition of their child's sample following screening use. Most importantly, the destruction of nearly 5 million NBS samples suggests that parents are not willing to unknowingly compromise their claims of privacy rights even for the sake of potential research progress.

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<sup>189</sup> Joint Stipulation of Dismissal with Prejudice, *Beleno v. Tex. Dept. of State Health Servs.*, No. SA09CA188-FB (W.D. Tex. Dec. 7, 2009); Compare Settlement Agreement, *supra* note 126, with *Beleno* Complaint, *supra* note 111, at 9-10.

<sup>190</sup> Settlement Agreement, *supra* note 126.

<sup>191</sup> *Id.* at 3-4.

<sup>192</sup> *Id.* at 4.

<sup>193</sup> H.B. Act of May 27, 2009, 81<sup>st</sup> Leg. R.S., Ch. 179, § 33.011, 2009 Tex. Sess. Law. Serv. Ch. 179 (Vernon).

<sup>194</sup> *Id.*; Settlement Agreement, *supra* note 126 (requiring the disclosure information relating to the uses of NBS samples and allowing parents to prohibit such uses).

## IX. THE ETHICAL VALUE OF AUTONOMY AND THE RIGHT OF PARENTS TO REFUSE THEIR CHILD'S PARTICIPATION

### A. Balancing Individual Dignitary Interests and a Research Agenda

Tarini's statistics and the parental responses in Minnesota and Texas suggest a disconnect between health departments' assumptions that they do not need to obtain consent for retention and research beyond screening.<sup>195</sup> In light of the Minnesota and Texas outcomes, other states are likely to still question whether the law permits collection for retention and research without consent on samples initially collected for screening use. It is likely that a state's interpretation will hinge upon whether they prioritize protections for human subject research, or whether they presume that constructive scientific action imbues a duty on society to contribute to research.

Some opponents of informed consent have expressed their belief that it will reduce the amount of NBS samples collected and thereby impede research efforts.<sup>196</sup> In a Minnesota House of Representatives floor discussion regarding the Genetic Privacy Act and whether consent was required for NBS collection in Minnesota, Representative Tina Liebling expressed her concern that a consent requirement would negatively impact the Mayo Clinic's ability to conduct research in the state.<sup>197</sup> Further, Kharaboyan and colleagues note that requiring consent may indeed negatively impact research because it could create selection bias based on parents who decline participation, which could potentially decrease the scientific value of the research.<sup>198</sup>

Resistance also stems from improperly balancing the interests of the individual to refuse participation against promoting a research agenda. Charlotte Harrison, a Fellow in Medical Ethics at Harvard

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<sup>195</sup> See Tarini et al., *supra* note 116.

<sup>196</sup> See Feuchtbaum et al., *supra* note 36, at 3, 11.

<sup>197</sup> See Amended Notice of Motion and the Motion to Dismiss, or in the Alternative, Motion for Summary Judgment on Plaintiffs' State Statutory Claim Based on Minn. Stat. § 13.386 Set Forth in Plaintiffs' First Amended Complaint at 10, *Bearder v. State*, Civil Action No. 27-CV-09-5615, (Minn. Dist. Ct. June 26, 2009).

<sup>198</sup> Kharaboyan et al., *supra* note 1, at 747.

Medical School who also holds a J.D., traced this balancing test to the holding of *Moore v. Regents of the Univ. of Cal.*,<sup>199</sup> which favored societal interests in potential scientific advancements over individual dignitary interests.<sup>200</sup> Senior Vice President of the Association of American Medical Colleges David Korn opines that “consent feels nice [and] letting people decide what’s going to happen with their tissue seems like the right thing to do.”<sup>201</sup> Korn further asserts that “[p]eople are morally obligated to allow their bits and pieces to be used to advance knowledge to help others. Since everybody benefits, everybody can accept the small risks of having their tissue scraps used in research.”<sup>202</sup> Korn’s assumption that individuals have a moral duty to contribute to research prioritizes his perception of the majority’s interest in advancing research. However, as David Hunter points out, benefit to the majority is not alone a sufficient interest to override individual autonomy.<sup>203</sup>

### **B. California Department of Health Services: Waiving Consent to Reduce Cost and Administrative Burden**

The California Department of Health Services echoed this problematic rhetoric that research should trump individual interests when it decided to retain NBS samples for additional research without con-

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<sup>199</sup> See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990) (holding that a patient did not have a property right in surgically excised spleen tissues from which doctors at the University of California had made significant profit from research conducted thereon).

<sup>200</sup> Charlotte Harrison, *Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 80 (2002).

<sup>201</sup> Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES, Apr. 16, 2006, § E (Magazine) at 45, available at [http://www.nytimes.com/2006/04/16/magazine/16tissue.html?\\_r=1&scp=1&sq=%22Taking%20the%20Least%20of%20You%22&st=cse](http://www.nytimes.com/2006/04/16/magazine/16tissue.html?_r=1&scp=1&sq=%22Taking%20the%20Least%20of%20You%22&st=cse). Korn’s discussion relates generally to the issue of consent for taking and using human tissue and blood samples for research.

<sup>202</sup> *Id.* Korn does admit a system should provide an exception for religious beliefs. *Id.* Yet Korn’s proposed allowance fails to account for the fact that in the instance of NBS, most parents are not even aware a state’s health department retains them, let alone shares them for future research, nor are the parents aware of any particular types of research that may be especially contrary to their religious beliefs.

<sup>203</sup> David Hunter, *One Time General Consent for Research On Biological Samples: Autonomy and Majority Rules Have Been Misunderstood*, 332 BRIT. MED. J. 665, 665–66 (2006); see also Drabiak-Syed, *supra* note 20, at 323–24 (discussing autonomy).

sent because obtaining consent impeded quick sample collection and was too costly.<sup>204</sup> Some health departments, such as the California Department of Health Services, have prioritized their public health research agenda over individual interests in an attempt to augment disease-identification and method-improvement research.<sup>205</sup> Although the agency most certainly operates according to beneficial motivations, benevolent intent does not negate a requirement for consent. In 2002, the Genetic Disease Services Branch (GDB) of the California Department of Health Services designed a pilot study protocol to use prospectively collected NBS samples with tandem mass spectrometry to research new testing methods and identify additional genetic conditions and disorders.<sup>206</sup> As a formal research investigation that planned to use prospectively collected NBS samples, the protocol required the hospital acting for the GDB to obtain parental consent before using a given NBS sample in the study.<sup>207</sup> Despite the GDB's attempt to communicate to the 299 maternity hospitals included in the study that their staff must obtain informed consent from parents, data revealed that many parents were not asked to participate because this process imposed a burden on hospital administration.<sup>208</sup>

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<sup>204</sup> Feuchtbaum et al., *supra* note 36, at 3, 8. Although this research occurred internally, it still constituted "research" because it was not a validation of current screening tests but rather development and testing new technologies using the NBS. When describing the protocol, Feuchtbaum et al. also use the term "research" and explain the Genetic Disease Services Branch (GDB) initially sought informed consent based on guidelines set forth by the Association of Public Health Laboratories (APHL). *Id.* at 5. An APHL position paper stated that a state health department should obtain consent for research studies where "a new assay or condition would be tested" and the new technology and its clinical utility had yet to be fully determined. *Id.*

<sup>205</sup> *Id.* at 3.

<sup>206</sup> *Id.* at 4.

<sup>207</sup> Feuchtbaum et al., *supra* note 36, at 5-6. Feuchtbaum et al. asserted that GDB could have obtained an IRB waiver under 45 C.F.R. § 46.102, paragraph b5 and should seek a waiver or exemption for future research studies that are designed to identify new screening tests. *Id.* at 11-12. However, while the language of this waiver applies to evaluation of current benefits or services and how they are offered, but it arguably does not extend to a comprehensive research protocol designed to develop additional tests in the area. *Id.*

<sup>208</sup> *Id.* at 6-7. Feuchtbaum et al.'s study revealed that the hospitals involved in the study did not always offer parents the option to enroll their newborn in the study. *Id.* Specifically: 31% of hospitals offered participation to between 50% and 74% of births; 23% offered participation to 75% or more births; and 21% of hospitals offered participation to no newborn parents. Feuchtbaum et al., *supra* note 36, at 7.

However, among parents that were asked to enroll their newborn in the study, over 90% consented.<sup>209</sup>

Summarizing the pilot project results, Feuchtbaum and colleagues concluded that parental consent to use NBS samples for research to identify new diseases using new technologies should be waived.<sup>210</sup> The GDB asserted that waiving consent for a pilot project would produce results faster and cost less.<sup>211</sup> This approach of not seeking consent would thereby minimize the administrative burden on the GDB of educating and recruiting maternal hospitals to obtain consent from parents to enroll their newborn in such a study. Feuchtbaum and colleagues concluded that “the legitimate needs of society and the interests of newborns should not be sacrificed to respond to the autonomy interests of the few parents who did not wish their infant to participate in the study . . . .”<sup>212</sup>

I argue that this type of situation where waiver is used as a creative mechanism to overcome administrative barriers does not meet the four formal criteria to obtain an IRB waiver for consent under the Common Rule. Based on this study’s findings, one implementing a method that includes seeking consent could anticipate an administrative burden on the hospital and health department and could thus plan consent implementation in the hospitals accordingly. Hence, this study’s results support the finding that programs should establish a method of efficiently obtaining consent for additional research. Notably, these results demonstrate that if parents are asked, the vast majority (over 90%) would likely consent.<sup>213</sup> Focusing on how to remedy the administrative setbacks and expressly asking parents has the potential to amass sample collections for research without using an IRB waiver based on convenience. Although the health department could arguably eliminate consent for screening in the interest of newborns’ health, its duty of beneficence to monitor and protect the health of

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<sup>209</sup> *Id.* at 7.

<sup>210</sup> *Id.* at 11.

<sup>211</sup> *Id.* at 8.

<sup>212</sup> *Id.* at 3.

<sup>213</sup> *Id.* at 7.

California citizens does not extend to unconsented research.<sup>214</sup>

### C. Preventing Erosion of Individual Rights: UK's Example

Adopting the premise that the importance of research should weigh more heavily than individual interests could even further erode consideration of individual interests. As an example, the UK's General Medical Council (GMC) has taken the above conclusions even more in the direction of wholly prioritizing research interests at the expense of individual rights, which raises significant ethical issues.<sup>215</sup> The GMC promulgated a Confidentiality Guidance document that provides recommendations relating to the disclosure and use of personal medical information for research.<sup>216</sup> This document contains several problematic points relating to the determination of when to disclose and share personal medical information without the consent of the individual. If it is impracticable to obtain consent for research and the public interest is greater than the harm to the individual, then the GMC advises identifiable information can be released without consent.<sup>217</sup> However, the document includes the possibility of sample bias arising from participant refusal within the definition of

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<sup>214</sup> Feuchtbaum et al. also problematically blur the distinction between screening and additional research throughout the results discussion, asserting that the GDB has a duty to protect the health of California citizens and the right to determine the benefit of a new test, and that parents may not have the best interest of their child in mind. Feuchtbaum et al., *supra* note 36, at 9. Although these statements may be true and may support the rationale for some screening tests without consent, they do not eliminate the need for parental consent for research following the established screening process. *Id.*

<sup>215</sup> See *Confidentiality Guidance: The Public Interest*, GEN. MED. COUNCIL ¶ 36-37 (2009), [http://www.gmc-uk.org/guidance/ethical\\_guidance/confidentiality\\_36\\_39\\_the\\_public\\_interest.asp](http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_36_39_the_public_interest.asp); *Confidentiality Guidance: Research and other Secondary Uses*, GEN. MED. COUNCIL ¶ 42-45 & nn. 15-18 (2009), [http://www.gmc-uk.org/guidance/ethical\\_guidance/confidentiality\\_40\\_50\\_research\\_and\\_secondary\\_issues.asp](http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_40_50_research_and_secondary_issues.asp).

<sup>216</sup> See *Confidentiality Guidance: The Public Interest*, *supra* note 215, ¶¶ 36-39, 40-50. Although this document addresses research generally, for the sake of argument this article extrapolates the GMC's principles of overriding refusal to consent the specific context of research using NBS. *Id.*

<sup>217</sup> *Confidentiality Guidance: Research and other Secondary Uses*, *supra* note 215, ¶¶ 41-44, at nn.15-18.

practicability.<sup>218</sup> This means that if the researchers believe that too many individuals would refuse participation, obtaining consent would be impracticable and they need not do so. The document further reiterates the notion of circumventing consent by stating that in exceptional circumstances it recommends disclosing personal medical information, even if subjects have refused consent, if the research would provide great public benefit.<sup>219</sup> Although the GMC's guidance only addresses research participation generally, the assumption that refusal for research participation should be overridden resonates with how minimizing individual interests could affect US research policies.<sup>220</sup>

Respect for autonomy and the purpose of human subject regulations require parental consent to retain and use NBS samples. Both the historical foundations of research ethics as well as developing doctrine relating to genetic material clearly state that subjects must provide express consent for research participation.<sup>221</sup> When elaborating on the concept of informed consent, the Declaration of Helsinki dictates that in human subjects research the interests of the subject must "take precedence over the all other interests."<sup>222</sup> United Nations Educational, Scientific, and Cultural Organization (UNESCO) re-

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<sup>218</sup> *Id.* at ¶ 43 n.18.

<sup>219</sup> *Id.* at ¶¶ 48-52 nn.19-22.

<sup>220</sup> See Elster, *supra* note 74, at 188-89 (citing Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786 (1995)); Kharaboyan et al., *supra* note 1, at 744 (arguing that such actions may undermine public confidence in screening programs). Both Elster (quoting Ellen Wright Clayton) and Kharaboyan et al. discuss how waiving consent even by review boards may still pose harm to participants. *Id.*

<sup>221</sup> See World Med. Ass'n Declaration of Helsinki, *Ethical Principles for Medical Research Involving Human Subjects*, 284 JAMA 3043, ¶¶ 20-26, 3044 (Oct. 2008), available at <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>; see also O'Brien *supra* note 34, at 200-01 (discussing informed consent requirements for human subject research); UNESCO, INTERNATIONAL BIOETHICS COMMITTEE, INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA, Vol. 1, at 42, 45 (Sept. 29-Oct. 17, 2009), available at <http://unesdoc.unesco.org/images/0013/001331/133171e.pdf#page=45>; Claude Laberge et al., *Newborn Screening, Banking, and Consent*, HUMAN GENETICS INT'L, at 4-7 (March 2003), available at <http://www.humgen.umontreal.ca/int/GE/en/2004-3.pdf> (arguing that informed consent is crucial for future NBS collection and screening policies).

<sup>222</sup> See World Med. Ass'n Declaration of Helsinki, *supra* note 221, at ¶ 6 (stating that "[i]n medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests").



quires that informed and express consent should be obtained for the collection of human genetic data, human proteomic data or biological samples.<sup>223</sup> Informed consent as a fundamental principle in research means that parents can decline to allow the state health department and associated researchers to retain and use their child's sample following screening, no matter how small the risk to the child or how great the potential benefit to society.<sup>224</sup> This right of refusal exists even if the consequence is that researchers are faced with burdens such as administrative setbacks to implement a consent procedure, potentially not obtaining a sufficient number or variety of samples to achieve statistical significance, or that the research would not meet its anticipated potential.<sup>225</sup>

#### **X. BYPASSING CONSENT WITH ANONYMIZATION FAILS TO MINIMIZE HARM**

As a compromise between promoting research and protecting individual interests, some scholars have suggested anonymizing samples as a means to disconnect NBS from the child and bypass parental consent.<sup>226</sup> However, this would circumvent any type of consent requirement and would ultimately still eliminate a parent's choice to decline participation on behalf of their child. Despite an attempt to recognize the newborn's individual interest in the NBS samples, this option still misses the primacy of the research subject because it subtracts the element of choice and could still pose additional harms to the newborn child.

Some scholars and researchers have suggested anonymizing samples would eliminate the requirement to obtain consent and

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<sup>223</sup> INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA, *supra* note 221 (stating that "[i]t is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought").

<sup>224</sup> See Edwards, *supra* note 37, at 650.

<sup>225</sup> See Thomas, *supra* note 123, at 276 ("[P]eople are entitled to refuse to participate, even if the consequence is that researchers may not be able to recruit sufficient participants to achieve statistical significance for the research.").

<sup>226</sup> See, e.g., Kharaboyan, *supra* note 1, at 747.

would still support a sufficient research agenda.<sup>227</sup> By anonymizing the samples, some argue samples are no longer personal, which thereby minimizes the risk of harm to the child to the extent that explicit consent from the parents is no longer required.<sup>228</sup> Although anonymized samples could be used for confirmatory studies or the development of new screening tests, other types of research such as epidemiological research or studying genetic components of the disease process may be better accomplished using either de-identified, coded, and or linked samples that would provide more information and annotations to the researcher.<sup>229</sup> Anonymization also eliminates the important right of parents to know how their child's sample will be used, potentially object, and request withdrawal.<sup>230</sup>

Anonymization should not be used as a creative means of amassing a collection of NBS samples for banking in the state health department nor for research sharing with associated entities. Kharaboyan and colleagues note that a distinction exists between using anonymous or archived anonymized samples and prospectively collecting samples for research following screening.<sup>231</sup> "[W]hereas consent is waived when archived samples are anonymized, to anonymize [NBS] without seeking consent at the time of collection for anticipated, anonymized research, is viewed by some as questionable and could undermine public trust in research."<sup>232</sup> Kharaboyan and colleagues argue that waiving consent for archived anonymous samples is less objectionable than prospectively collecting new samples for banking and research without consent with the option of anonymization.<sup>233</sup> Such circumvention of the consent requirement disingenuously applies its purpose because, according to federal guidance, sample banking (inclusive of unanticipated future research)

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<sup>227</sup> See, e.g., *id.* at 744.

<sup>228</sup> *Id.* ("[I]f [NBS] are not identifiable then they are not 'personal' and data-subjects consequently stand only a very low risk of being harmed.")

<sup>229</sup> See Thomas, *supra* note 123, at 271-72 (suggesting different research uses for NBS and whether such samples should be anonymized or identified).

<sup>230</sup> *Id.* at 276.

<sup>231</sup> See Kharaboyan, *supra* note 1, at 744.

<sup>232</sup> *Id.*

<sup>233</sup> See *id.*

constitutes human subjects research governed by federal regulations.<sup>234</sup>

However, even if researchers intend to use anonymization as a means of protecting newborn participants, actual practices may not comport with this method. Merz and colleagues' research demonstrates "that researchers using human tissue samples without consent or IRB approval were more likely to use samples in an identifiable form rather than in the proper anonymized form."<sup>235</sup> This finding highlights the problematic reality that planning to anonymize samples as a means of bypassing consent intending to protect subjects' rights could actually further undermine these rights. Whether researchers do not take precaution to properly anonymize samples or they mistakenly think samples have been previously anonymized, the newborn's parents may not even know the samples are even being used for research and would not have the option to object and withdraw.<sup>236</sup>

Assuming samples are correctly anonymized, the nature of a blood sample containing DNA as well as the advancement of technology further undermine the argument that merely stripping the sample of legally defined identifiers renders it unidentifiable. Even if the newborn's name and identity are removed from the sample, anonymization cannot fully strip the sample of its connection to the infant.<sup>237</sup> DNA is arguably the ultimate identifier based on the amount of information it provides relating to an individual.<sup>238</sup> As technology

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<sup>234</sup> See Mark Barnes & Kate Gallin Heffernan, *The "Future Uses" Dilemma: Secondary Uses of Data and Materials by Researchers and Commercial Research Sponsors*, 3 MED. RES. L. & POL'Y REP. 440, 446 (June 6, 2004) ("[T]he mere creation and maintenance of databases or other specimen repositories meet the definition of 'research' under the HIPAA regulations.").

<sup>235</sup> Edwards, *supra* note 37, at 646 (referencing Merz et al., *IRB Review and Consent in Human Tissue Research*, 283 SCI. 1647 (1999)) (In reviewing thirteen studies performed without consent or IRB approval, only three (23%) used nonidentified samples).

<sup>236</sup> See Olney et al., *supra* note 2, at 621 (noting that based on their study's results only 16% of state respondents indicated parents are informed that their child's NBS may be used for further research).

<sup>237</sup> Edwards, *supra* note 37, at 671 (noting that the biological connection (such as the DNA sequences) between the tissue donor and the sample can never be erased).

<sup>238</sup> See Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 7, 16-17 (2006) (discussing the information provided by DNA).

increases and scientists achieve greater understanding of the genetic code, DNA will likely become even more closely identified with an individual.<sup>239</sup>

Although the state health department or associated researchers can anonymize the samples, this action may not prevent group harm or individual stigmatization. Even without a link to a child's individual identity, research involving genes associated with group membership could pose a threat to children who are members of that specific group.<sup>240</sup> If children belong to a minority or marginalized group, the public may heuristically attribute negative health issues with that group membership.<sup>241</sup> The use of race or ethnicity in studies that may provide important information on disease occurrence within a population subset could also reinforce false biological differences between groups and potentially contribute to discrimination against newborns belonging to that group.<sup>242</sup> Thus, "even [when samples are] anonymized they are not neutral to their source."<sup>243</sup> Parents may oppose certain uses of the NBS for fear of it causing their child to be stigmatized or parents may want to exclude their child's sample from certain uses if those uses would run contrary to their personal convictions.<sup>244</sup>

## XI. CONCLUSION

NBS stored at state health departments after newborn screening represent a significant potential resource for researchers seeking access to a wide collection of banked blood. Federal initiatives and national associations recognize the immense value of these banks and call for the development and utilization of NBS for research purposes. However, state law and state health departments must recog-

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<sup>239</sup> Edwards, *supra* note 37, at 671.

<sup>240</sup> Laberge et al., *supra* note 221, at 5 (noting particularly problems associated with discrimination and stigmatization if a donor eventually tests positive for a certain condition).

<sup>241</sup> *See id.*

<sup>242</sup> Goldenberg, *supra* note 4, at 97.

<sup>243</sup> Thomas, *supra* note 123, at 273.

<sup>244</sup> *See id.* at 275.

nize that screening is distinct from banking and other additional research use. State legislatures and health department policy should classify this practice as human subjects research, require it to comport with federal regulations, and re-think how to apply federal regulations based on research that undermines our previous assumptions relating to identifiability. Currently, the majority of states have enacted neither legislation nor supplementary policies recognizing this distinction. Most states do not inform parents that the health department will retain their child's sample or use it for additional research, and few states obtain consent for research using NBS. As such, parents lack the ability to decline their newborn's participation in research. States such as Minnesota and Texas that do have specific statutory requirements still present significant uncertainty when interpreting referential applicability between the genetic privacy and newborn screening sections, as well as construing statutory terms. Opposing interpretation of the statutes in *Bearder* and *Beleno* highlight that bypassing consent violates important dignitary and legal interests. Despite the varied outcomes of these two cases, upholding the foundation of the Common Rule means an individual's interest in refusing participation cannot be sacrificed to promote a research agenda. Research on public attitudes demonstrates that when parents are asked, the majority will provide consent to their child's NBS for research.<sup>245</sup> Thus, instituting a consent policy in statutory law and health department procedures would amass a robust annotated collection while minimizing dignitary harm to newborn participants.

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<sup>245</sup> Feuchtbaum et al., *supra* note 36, at 37; Tarini et al., *supra* note 116, at 3.