"THE LIFE OF THE FLESH IS IN THE BLOOD"[1]: STATE STORAGE AND USAGE OF BABY'S BLOOD SAMPLE

JACLYN S. D'ARMINIO[2]

INTRODUCTION

The maternity ward of any hospital is filled with the chaos and joy of new parents welcoming newborns into the world. From the moment they are freed from their mothers' wombs to the moment they go home, newborns are subjected to a battery of tests. The baby is weighed and measured. Hearing, sight, and reflexes are tested. All while Mom and Dad look on. One of the more memorable tests for parents happens in the first day of the baby's life. The test is simple; it involves a small prick to the heel and a few drops of blood collected on a piece of paper.[3] Mom and Dad may remember being told that the test is mandated by law, and it screens for more than thirty different metabolic disorders, most of which are treatable.[4] After the test, the baby's tears are dried, a bandage is put in place, and the baby goes home with the new parents.

These Newborn Screening ("NBS") programs provide a valuable service to the state and to the parents whose children might have an otherwise undiagnosed metabolic disorder.[5] However, what most parents do not realize and are never told, is that there is a chance that the baby's bloodspots are sitting in a climate-controlled biobank, and in some states, the results will sit there indefinitely.[6] These biobanks

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[1] *Leviticus* 17:11.

[2] J.D. Candidate, May 2012, Benjamin N. Cardozo School of Law; B.S. 2009, Cornell University. The author would like to thank Professor Daniel Ravicher for his assistance and comments. She would also like to thank Amy Schere and James Strassner for their assistance in deciphering the scientific concepts. Finally, a special thanks to her mother, Wendy, father, Tom, sister, Lauren, and loving partner, Andrew, for their patience and support.

[3] *See Neonatal Screening: Blood Specimen Collection and Handling Procedure*, MINN. DEP'T OF HEALTH, http://www.health.state.mn.us/newbornscreening/docs/heelstick.pdf (last visited Jan. 1, 2011) (describing the heel prick procedure for retrieving the blood samples for the Newborn Screening tests).

[4] *See Newborn Screening Tests*, KIDS HEALTH, http://kidshealth.org/parent/system/medical/newborn_screening_tests.html# (last visited Jan. 1, 2011) (providing basic information for parents about the newborn screening tests including the most common diseases tested for and the treatments available for them).

[5] *See id.*

[6] *See* Bradford L. Therrell, Alissa Johnson & Donna Williams, *Status of Newborn Screening Programs in the United States*, 117 PEDIATRICS S212, S219 (2006).

are valuable to scientific researchers who might wish to access the samples, and to whom this access is sometimes granted.[7]

This Note discusses the ethical, legal, and policy issues that can arise from this practice of storing NBS samples. Part I will examine the history of state NBS programs, variations from state to state in the policies surrounding the storage and use of residual blood spots, public opinion and knowledge of the programs, as well as the pertinent federal legislation surrounding the topic. Part II will examine the only lawsuit concerning newborn bloodspots, and will discuss one line of precedent that may act as a roadblock for future lawsuits concerning NBS programs. Part II will also examine a potential point on which the cases may be distinguished from the NBS cases. It will conclude by exploring possible policy initiatives and changes which might allow for the increased comfort of parents and communities around the storage and control of the bloodspots, while allowing for the continued usage of newborn bloodspots in research.

Scientific evidence and two recent lawsuits suggest that parental concern over the control, storage, and usage of these bloodspots without proper safeguards endangers both scientific advancement and the children the tests were meant to protect.[8] These concerns could result in a growing number of parents opting out of screening programs and putting their children at risk for devastating diseases. Although the state has a strong line of precedent which would allow it to continue its practices uninhibited by the courts, it is imperative that new policies and procedures, specifically ones surrounding informed consent, be put into place so as to allow the NBS program to both protect children and act as a tool to further scientific inquiry.

I. BACKGROUND

A. Dr. Robert Guthrie's Legacy

Since the 1960's, NBS programs have been implemented across the fifty states as well as throughout the international community.[9] These relatively non-

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[7] "Maryland, Wyoming and District of Columbia require that parents be given the option to consent to screening." *Id.* at S216.

[8] *See generally id.*; Linda Kharaboyan, Denise Avard & Bartha Maria Knoppers, *Storing Newborn Blood Spots: Modern Controversies*, 32 J.L. MED. & ETHICS 741, 742 (2004); David Kaufman, Juli Murphy-Bollinger, Joan Scott & Kathy L. Hudson, *Public Opinion about the Importance of Privacy in Biobank Research*, 85 AM. J. OF HUMAN GENETICS 643 (2009); Kathryn E. Fant, Sarah J. Clark & Alex R. Kemper, *Completeness and Complexity of Information Available to Parents From Newborn-Screening Programs*, 115 PEDIATRICS 1268, 1270 (2005); Erin Rothwell, Rebecca Anderson & Jeffrey Botkin, *Policy Issues and Stakeholder Concerns Regarding the Storage and Use of Residual Newborn Dried Blood Samples for Research*, 11 POL'Y, POL. & NURSING PRAC. 5, 6 (2010). *See also* Bearder v. State, 788 N.W.2d 144 (Minn. Ct. App. 2010); Complaint, Beleno v. Tex. Dep't of State Health Servs., No. 09-00188 (W.D. Tex. 2009).

[9] Countries with NBS programs include, but may not be limited to, Australia, France, Germany, Canada, the Philippines, Ireland, Japan, Thailand, the United Kingdom, Brazil, Italy, and the Netherlands. *See International NBS Programs*, NAT'L NEWBORN SCREENING & GENETICS RESOURCES CTR., http://genes-r-us.uthscsa.edu/resources/newborn/international.htm (last visited Jan. 16, 2011).

invasive blood tests began with the work of Dr. Robert Guthrie who invented a screening test for phenylketonuria ("PKU"),[10] a genetic disorder causing an inability to produce a specific enzyme and which results in a buildup of the amino-acid phenylalanine.[11] The buildup of phenylalanine has a wide range of devastating symptoms, including stunted growth, seizures, and mental retardation.[12] If diagnosed early enough, PKU is highly treatable and most, if not all, of the symptoms can be avoided or reversed by constricting the amount of protein, and thus phenylalanine, in the daily diet.[13] Dr. Guthrie's work made the detection of this metabolic disorder within the first days of human life possible.[14]

The procedure for the test developed by Guthrie is simple. Within the first month of life, usually within the first twenty-four hours, three to five droplets of blood are collected on special filter paper.[15] Trained hospital personnel prick the newborn on the middle of its heel with either a needle or, more commonly, a lancet,[16] and collect the required amount of blood by pressing the heel to the filter paper.[17] The paper is attached to the newborn's basic medical information, allowed to dry, and sent to a laboratory for testing while the newborn is safely returned to its parents.[18] Families with newborns who have PKU can receive the results of these tests within days,[19] allowing them to take immediate action and put into place the requisite diet.

Shortly after Dr. Guthrie invented the PKU test and proved that newborn screening was effective in preventing the PKU symptoms, states began adopting mandatory PKU screening laws and opening public health laboratories.[20] Since the blood collected for the original PKU test was usually collected in higher amounts

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[10] *See Overview Newborn Screening*, NAT'L NEWBORN SCREENING & GENETICS RESOURCE CTR., http://genes-r-us.uthscsa.edu/resources/newborn/overview.htm (last visited Jan. 1, 2011).

[11] *See Phenylketonuria, Definition*, THE MAYO CLINIC, http://www.mayoclinic.com/health/phenyl ketonuria/DS00514 (last visited Jan. 1 2011).

[12] *See Phenylketonuria, Symptoms*, THE MAYO CLINIC, http://www.mayoclinic.com/health/phenyl ketonuria/DS00514/DSECTION=symptoms (last visited Feb. 13, 2012).

[13] *See id.*

[14] *See* Harvey Levy, *The History of Newborn Screening*, NEW ENGLAND CONSORTIUM OF METABOLIC PROGRAMS, http://www.newenglandconsortium.org/flashcast/nbs_home.html (last visited Jan. 1, 2011) (recorded video lecture and slides by Dr. Harvey Levy, Senior Associate in Medicine at Children's Hospital Boston, and Professor of Pediatrics at Harvard Medical School. The lecture discusses the history of newborn screening from the discovery of errors of inborn metabolism in the early 1900s to modern day screening methods and public health approaches).

[15] *See Neonatal Screening: Blood Specimen Collection and Handling Procedure*, *supra* note 3.

[16] "A sharp-pointed and commonly 2-edged surgical instrument used to make small incisions." *Lancet*, MERRIAM WEBSTER DICTIONARY ONLINE, http://www.merriam-webster.com/dictionary/lancet (last visited Jan. 16, 2011).

[17] *See Neonatal Screening: Blood Specimen Collection and Handling Procedure*, *supra* note 3.

[18] *See id.*

[19] *See Parent and Family Resources: Frequently Asked Questions about Newborn Screening*, NAT'L NEWBORN SCREENING & GENETICS RESOURCE CTR., http://genes-rus.uthscsa.edu/ parentpage.htm (last visited Jan. 1, 2011).

[20] *See* Levy, *supra* note 14.

than necessary,[21] early NBS programs were easily expanded to include other disorders.[22] Furthermore, since the tests were not extraordinarily invasive and proved to be highly effective in quickly identifying those infants in need of nutritional management, public health interest increased, which allowed for the rapid growth in the number of metabolic diseases for which infants were tested.[23] Today, Dr. Guthrie's legacy remains in the name of the cards he invented—the "Guthrie Card"—which allow the blood samples of every newborn child to be easily collected, tested, and stored.[24] These cards are now used in every NBS program to test for, in some states, more than thirty metabolic disorders.[25]

B. From Bloodspots to Biobanks

The vast majority of babies born in this country participate in such blood screenings.[26] Most babies come through with a clean bill of health; those that do not are provided with the information needed to manage the identified disease or diseases.[27] In 2001, all fifty-one programs[28] reported a greater than ninety percent parental compliance rate with their NBS program.[29] As explained above, only a small amount of blood is actually used for the testing process.[30] Even with the accelerating number of disorders being tested, a large amount of the blood collected remains untainted.[31] Consequently, state regulators and the laboratories they run are left with a pressing decision concerning what to do with the remaining samples.

A recent study of state NBS programs found that of the fifty-one NBS programs, only nine states had specific written requirements for the retention of the blood spots and the test results.[32] Furthermore, twenty-eight of the programs had no written policy about the usage of the residual specimens.[33] The survey of the state laboratories showed that twenty-four of the programs reported storing the

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[21] This was done so that if retesting was necessary, or contamination was expected there were backup samples available for use. *See id.*

[22] *See id.*

[23] *See id.*

[24] *See id.*

[25] *See id.*

[26] *See* Therrell, *supra* note 6, at S217.

[27] For example, the rate of incidence of PKU in the United States is reported as 1 in 10,000 to 15,000 births. However, it should be noted that at this time the author of this Note is unable to confirm by scientific study this rate of incidence. The most reliable source for this information comes from the Utah Dep't of Health's website. *See Newborn Screening Program: Statistics*, UTAH DEP'T OF HEALTH, http://health.utah.gov/newbornscreening/Statistics/Statistics.htm (last visited Jan. 16, 2011). The Utah Dep't of Health also cites the national rate for Galactosemia as 1 in 40,000 to 60,000 and the rate of Congenital Hypothyroidism as 1 in 4,000. Again, the author of this Note is unable to confirm these numbers in any substantial manner leading her to assume that there has not been a recent study compiling this data from the various NBS programs.

[28] Every state in the United States has a newborn screening program, as does Washington DC.

[29] *See* Therrell, *supra* note 6, at S217.

[30] *See* Levy, *supra* note 14.

[31] *See id.*

[32] *See* Therrell, *supra* note 6, at S219.

[33] *See id.*

samples for less than six months;[34] six programs stored their specimens for more than eighteen years; and eight programs stored them "indefinitely."[35]

The storage of these blood spots can serve a number of purposes. Primarily, they can be used for a confirmation of diagnosis and further testing.[36] This can include identifying false positives or negatives or determining an effective intervention for children suffering from an identified condition.[37] They may also provide valuable insight in cases of Infant Death Syndrome.[38] Sometimes the blood spots are used for the continued development of other testing methods as well as regular quality assurance checks, and most state laws specifically allow for this kind of maintenance.[39] Alternatively, these specimens can be used for forensic or legal purposes, such as indentifying a kidnapped or deceased child, identifying criminals, or revealing paternity.[40] Finally, any specimen being stored for any length of time is going to be of interest to researchers of all kinds.[41] The sheer quantity and utility of these blood specimens make them a treasure trove of biological, medical, and genetic information on essentially the entire juvenile population of the United States.

The resulting storage of these bloodspots for an extended period of time can be perceived as a biobank. A biobank is an umbrella term for any "collection of human tissue samples and medical information about donors, which are stored for long periods of time[s] and used for research studies."[42] In their purest form, biobanks exist from the voluntary contributions of individuals, and they normally contain tissue samples as well as information about the subjects' medical and family history.[43] Presumably, in such a case, informed consent is taken from each prospective donor.[44] This ideally entails explaining how the donor's sample will and will not be used, as well as who may have access to the biobank.[45] Finally, an

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[34] *See id.*

[35] Of the remaining states, six store specimens for one year, and seven store specimens between two and seven years. *See* Therrell, *supra* note 6, at S219.

[36] *See* Kharaboyan, Avard & Knoppers, *supra* note 8, at 742.

[37] *See id.*

[38] *See id.*

[39] *See id.*

[40] *See id.*

[41] *See id.*

[42] *What is a biobank?*, GENETIC ALLIANCE REGISTRY AND BIOBANK, http://www.biobank.org/english/View.asp?x=1425 (last visited Jan. 1, 2011).

[43] *See id.*

[44] *See id.*

[45] *See id.*

Institutional Review Board ("IRB")[46] protects the biobank because it acts as a gatekeeper to the types of research for which the biobank is available.[47]

The aforementioned institutional safeguards for biobanks help quell public fear about the misuse of biological materials and encourage voluntary participation in the creation of biobanks. A recent study examined the American public's view on the possibility of a large-scale biobank and how various changes in the biobanking process would encourage greater contributions.[48] Interestingly, the study showed that when asked about the types of entities people were concerned about having their samples and information, seventy-five percent of respondents indicated that they were concerned over government control, whereas only fifty-six percent were concerned over private researchers having control of personal information.[49] Further, ninety-two percent of the study participants agreed to allow academic and medical researchers to submit research projects using biobank samples, twelve percent higher than those who would agree to allow government researchers to use the same samples.[50]

The study also examined participants' preferences for consent. Research participants overwhelmingly[51] responded that being asked for consent made them feel "respected and involved," and nearly three-quarters of the participants suggested it would make them feel that they "had control" over the samples.[52] When asked about types of consent,[53] forty-eight percent felt comfortable with a blanket consent form for all research approved by an oversight panel, in comparison to forty-two percent of those who wanted to be asked prior to every research project.[54]

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[46] "(g) Institutional Review Board (IRB) means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase institutional review committee as used in section 520(g) of the act." 21 C.F.R. § 56.102 (2009).

[47] *See What is a biobank?*, *supra* note 42.

[48] *See* David Kaufman, Juli Murphy-Bollinger, Joan Scott & Kathy L. Hudson, *Public Opinion about the Importance of Privacy in Biobank Research*, 85 AM. J. OF HUMAN GENETICS 643 (2009).

[49] *See id.*

[50] 75% of participants stated they would allow pharmaceutical company researchers to use their samples, and surprisingly 49% said that so long as their samples were de-identified the information and research could be made available "on the internet to anyone." Kaufman, Murphy-Bollinger, Scott & Hudson, *supra* note 48, at 647.

[51] *See id.* at 636.

[52] *Id.* at 647.

[53] This research question was examining the extent to which the subjects felt they should be involved in deciding which research studies should have access to their tissues and/or information. An action of blanket consent happens once, at the time in which the tissue is deposited, and covers any and all research the review board allows. Varying from blanket consent is a situation where a biobank donor consents to all areas of research but declines to allow participation in specific areas of research. Finally, the extreme form of consent would be a requirement that the biobank obtain consent every time the donor's tissue might be utilized in a research study. *See id.*

[54] The remaining 10% selected the option to opt-out of those categories of research for which they would not like to participate. *See id.*

What is particularly salient about this study is an indication of mistrust for government control and use of biobanks. Although the majority of participants would have allowed the government to utilize the biobanks, they appeared significantly more concerned about the government—as opposed to some private entity—having that control.[55] Since NBS biological specimens remain in the control of the government, and it is the government that makes decisions about which researchers may have access to them, it is important to acknowledge that these types of public opinion studies indicate a need for more, rather than fewer, safeguards.

II. CURRENT STATE POLICIES AND THEIR DISTANCE FROM PUBLIC OPINION

Despite the apparent public opinion in favor of informed consent, only three states require the informed consent of the parents before NBS; the majority of the state NBS programs do not have a formalized consent process.[56] Instead, most states utilize an opt-out form of consent rather than one that requires parents to opt-in after being adequately informed.[57] Opt-in consent requires parents to knowingly agree to participation in the continued storage[58] and possible dissemination of their baby's blood spots by requiring that the bloodspots not be continually stored or disseminated without the express permission to do so.[59] Opt-in systems rest on the idea that the default disposition should be to destroy every infant's bloodspots after the blood tests have been completed, unless otherwise provided by the parent.[60] In contrast, opt-out consent assumes that unless the parents specifically ask for the bloodspots to be destroyed, they have consented to the continued storage and presumed use of those bloodspots in research studies approved by the state.[61]

This opt-out only format becomes more troubling when parents are either denied the right to refuse the tests entirely, or, if they retain that right, are not adequately informed as to the full ramifications surrounding the choice of refusal. A recent study found that of the forty-seven programs that submitted materials to the study, five do not permit refusal of the screening tests.[62] Moreover, of those that permit refusal, only twenty-three programs mention the parents' right to refuse

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55 *See id.* The aforementioned article does not address or hypothesize why this might be but its importance in this discussion about NBS and bloodspot storage cannot be ignored in the conversation about the proper use of these specimens.

56 States with opt-in informed consent programs include District of Columbia, Maryland and Wyoming. *See* Therrell, *supra* note 6, at S220.

57 *See id.*

58 *See id.* For the purpose of this Note, continued storage of the bloodspots is considered by this author to be any length of time past which the primary purpose of these bloodspots no longer requires the storage of the actual blood, approximately 2 years.

59 *See* Therrell, *supra* note 6, at S220.

60 *See id.*

61 *See id.*

62 Michigan, Minnesota, Montana, Nebraska, and South Dakota. *See id.*

in their education material.[63] Additionally, only five programs mention the continued storage of samples in their educational material.[64]

The justification given for the lack of required consent concerning the screening program is that it is a public health issue, and the state's interest in identifying these treatable diseases outweighs the personal privacy interests of the parents and their newborns.[65] While this may be an acceptable justification for the screening program itself, issues arise when the state's interest in identifying the disease becomes obsolete,[66] and research becomes the state's primary interest. If it is important to the scientific community to have access to these biobanks of NBS blood samples, the state's primary objective should be the protection of these samples from misuse and abuse.

As discussed above, when given the opportunity to consent to biobank research, people have indicated that they are likely to participate provided that they feel secure in the procedures of the biobank.[67] In a recent study, potential stakeholders of the NBS program biobanks—including parents, doctors, and researchers—all indicated that informed consent should be obtained before samples are retained for extended periods of time and openly available for research.[68] Ignoring the presence of these values in the community, as well as the perceived possibility of abuse of these samples, may only promote distrust in the NBS programs itself. As more parents are made aware that they have the opportunity to opt-out of the testing, they may choose to not allow their newborn to be screened in order to prevent their baby's blood sample from being placed on file with the NBS program. This prevents their children from the diagnosis and lifesaving treatment they may need, and the state's public health interest is no longer being met. [69]

A. Pertinent Federal Statutes

To date, there are no binding federal regulations on state-based NBS programs. Although the federal government established the Advisory Committee on Heritable Disorders in Newborns and Children ("ACHDNC") in the Newborn Screening Saves Lives Act ("NSSLA"), the committee is merely in charge of handing out grants to researchers who study ways of improving and increasing

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[63] *See* Fant, Clark & Kemper, *supra* note 8, at 1270.

[64] Of those five, three indicated that the stored materials may be used for research. The other two indicated that the materials will not be used for any other purpose without request or prior consent. The study does not examine how often these materials are actually explained or even given to the new parents at the time of screening. *See id.*

[65] *See* Rothwell, Anderson & Botkin, *supra* note 8, at 6.

[66] The state's interest becomes obsolete after notification is made to parents concerning the test results, a reasonable amount of time has passed for follow up testing, and the newborn has made it past the ages commonly associated with Sudden Infant Death Syndrome in which re-testing of the Infant's blood sample may be considered reasonable. Approximately 2 years.

[67] *See* Kaufman, Murphy-Bollinger, Scott, & Hudson, *supra* note 48, at 643.

[68] *See* Rothwell, Anderson & Botkin, *supra* note 8, at 8.

[69] *See id.*

NBS.[70] The ACHDNC can also make recommendations on the best practices for NBS programs, but it has no actual power to enforce such practices.[71]

Notably, the federal government has established guidelines for the proper use of human subjects in experimentation.[72] These guidelines discuss research with human tissue and include requirements for institutional review boards ("IRB") and informed consent. Known as the "Common Rule," 45 Code of Federal Regulations section 46 applies to "all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research."[73] Thus, this statute should bind any state that receives federal grants under the aforementioned NSSLA if it accepts federal funding and allows for newborn bloodspots to be used in research.

The Common Rule requires that all human subject research be approved by an IRB, and be subject to the requirements of informed consent under 45 C.F.R. section 46.116. These requirements, however, are limited by the definition of a "human subject"[74] defined in section 46.102(f), in pertinent part, as

> [A] living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. . . . Private information includes information [which] . . . has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable . . . in order for obtaining the information to constitute research involving human subjects.[75]

Research on human tissue maintains its status as human subject research so long as that tissue is linked to materials which make it possible to identify the donor.[76] The Office for Human Research Protections in the Department of Health and Human Services ("OHRP") has stated that the kind of research to which the

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[70] *See* 42 U.S.C. § 300b-10 (2008).

[71] *See id.*

[72] *See* Protection of Human Subjects, 45 C.F.R. § 46.101 (2005).

[73] *Id.* § 46.101(a).

[74] A state's retention of newborn bloodspots does not in itself constitute human research. States have an individual and legitimate statutory purpose for the collection and testing of these blood samples, one for which most states do not require parents' informed consent. However, once states assume control over these samples and the ability to distribute them, states who accept federal funds for their NBS programs should be putting in the requisite safeguards under the Common Rule. Even if they are only providing NBS samples in de-identified form, it would be pertinent for them to place in writing their policies about the dissemination of the samples so that there are safeguards against abuse and an opportunity for the review of procedures if abuses come to light. As of 2006, only twenty-three states had written policies about the usage of the stored specimens. Fifteen had specific statutory language dealing with the use of specimens. It is not indicated how many specifically have written policies about how to ensure the de-identification of samples provided. *See* Therrell, *supra* note 6, at S219.

[75] 45 C.F.R. § 46.102(f) (2005).

[76] *See* DEP'T OF HEALTH AND HUMAN SERV. OFFICE FOR HUMAN RESEARCH PROT., GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS 3 (2008).

Common Rule does not apply is research where the investigator is not readily able to ascertain the identity of the individual from the information given to him.[77] The OHRP leaves the determination of whether the data is considered "coded"[78] to those institutions dealing in providing specimens or available personal data; however, it strongly recommends that the institution develop written policies for this determination.[79]

B. The Case Law and Precedent

1. Bearder v. State of Minnesota

The consequence of ignoring parental concerns over consent became increasingly clear when a group of parents sued the state of Minnesota, the Minnesota Department of Health ("MDH") and the Minnesota Commissioner of the Department of Health in the summer of 2009.[80] In *Bearder v. State of Minnesota*, the plaintiffs, all parents of minor children, sued for injunctive relief under claims of tortious conduct, violation of the constitutional right to privacy, taking without just compensation, and violation of the statutory right to privacy of genetic information under the Genetic Privacy Act ("GPA").[81] The plaintiffs' primary complaint was that the defendants stored newborn blood and genetic information acquired as part of NBS programs, and shared it with other entities without written and informed consent of the minors' parents.[82]

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[77] *See id.*

[78] Coded Data is data that is coded in such a way that would readily ascertain the research participant to whom the data pertains. This is usually done by developing a key which separates the personal information from the research data. This key allows data that has previously been stripped of identifying markers to be re-identified. A de-coded data set occurs when that key is purposefully made no longer accessible by anyone. A data set can still remain coded but considered de-coded if the control over the data set key remains outside of the control of the researcher. *See id.* In the case of newborn bloodspots, if the state provides the blood spots un-coded, meaning with identifying information, the data set would fall under the Common Rule for informed consent. However, if the state codes the information and retains the key, the data would be considered de-coded for the purposes of the study.

[79] *See id.*

[80] *See* First Amended Complaint, Bearder v. State, 788 N.W.2d 144 (Minn. Ct. App. 2010) (No. 09-5615). Since the writing of this Note, the Supreme Court of Minnesota has reversed the opinion of the district court and court of appeals, as explored in this section, determining that the newborn blood spots do constitute "genetic information" as found under the Genetic Protection Act and therefore the consent procedures put into place fail to adequately protect the bloodspots under that act. Bearder v. State, 806 N.W.2d 766 (Minn. 2011). However, the Supreme Court of Minnesota did not address the tissue ownership cases as explained in Part II.C of this Note. As of January 2012, the state has begun destroying all newborn bloodspots collected after November 16, 2011. Press Release, Minn. Dep't of Health, Minn. Dep't of Health to Begin Destroying Newborn Blood Spots in order to Comply with Recent Minnesota Supreme Court Ruling (January 31, 2012), *available at* http://www.health.state.mn.us/news/ pressrel/2012/newborn013112.html. Two additional law suits are still pending. *Id.* The author of this note is pleased to acknowledge this change, but chooses to leave this section of this Note intact as the Genetic Protection Act is unique to Minnesota providing newborns greater protection only in the state of Minnesota. The arguments used, and explained below, as well as the arguments discussed in Part II.C, are still available to other states and courts in future litigation.

[81] *See id. See generally* MINN. STAT. § 13.386 (2010) (conferring a statutory right to privacy of genetic information).

[82] First Amended Complaint, *supra* note 80.

In Minnesota, the NBS statute charges the Commissioner of Health with the power to determine and revise which tests are to be performed.[83] Additionally, it mandates that parents shall be advised

> (1) [T]hat the blood or tissue samples used to perform testing thereunder as well as the results of such testing may be retained by the department of health, (2) the benefit of retaining the blood or tissue sample, and (3) that the following options are available to them with respect to the testing: (i) to decline to have the tests, or (ii) to elect to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing.[84]

Significantly, the statute does not offer any form of informed consent to the parents, nor does it mandate that parents receive educational material on the testing procedure itself or on the continued storage of their baby's bloodspots. It merely mandates that parents be advised that they can opt-out of the screening by written request, and that if they do not opt-out of the screening, they can elect to have the tests destroyed.[85] The only other requirements under the Minnesota Statute are that the commissioner makes notifications and referrals to physicians and parents when a positive test is determined, maintain a registry of the confirmed positives, and prepare a system for parents or adult individuals to request the bloodspots to be destroyed and then, utilizing that system, comply with those requests.[86]

In *Bearder*, the plaintiffs argued that without any form of statutory authority and without informing parents, the MDH began to store the NBS samples for an undefined period of time.[87] Further, MDH allowed the samples to be used in not only their own public health studies but those of outside independent research organizations as well.[88] Although the defendants claimed that the samples being provided were being de-coded,[89] there was no written de-coding process.[90] In fact, evidence uncovered during discovery suggested that in one such study, despite de-

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[83] *See* MINN. STAT. § 144.125 (2010).

[84] *Id.*

[85] *See id.*

[86] "144.128 Commissioner's Duties: [t]he commissioner shall: (1) notify the physicians of newborns tested of the results of the tests performed; (2) make referrals for the necessary treatment of diagnosed cases of heritable and congenital disorders when treatment is indicated; (3) maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services; (4) prepare a separate form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed; (5) comply with a destruction request within 45 days after receiving it; (6) notify individuals who request destruction of samples and test results that the samples and test results have been destroyed; and (7) adopt rules to carry out sections 144.125 to 144.128." MINN. STAT. § 144.128 (2006). It should be noted that there are no sections between § 144.125 and § 144.128.

[87] *See* Plaintiffs' Memorandum of Law, Bearder v. State, 788 N.W.2d 144 (Minn. Ct. App. 2010) (No. 09-5615).

[88] *See id.* at 10.

[89] A process which theoretically would negate any purpose for retrieving informed consent from the parents prior to the study. *See supra* text accompanying note 78.

[90] *See* Plaintiffs' Memorandum of Law, *supra* note 87.

coding practices being utilized, it was still possible to identify some of the children in the study.[91]

The plaintiffs' most powerful argument contends that the existence of the GPA makes the collection, storage, use, and dissemination of the blood specimens—beyond the extent to which they are provided for in the NBS statute—an illegal act because Minnesota's Department of Health failed to get written informed consent as required by the GPA.[92] The GPA structure indicates that it is supposed to provide extended safeguards surrounding a person's genetic information, enforcing a standard of consent on research within the state that concerns genetic information.[93] Under the GPA, any collection of "genetic information" by a government entity may only occur after the individual has given written informed consent, and the use and storage of that material is restricted by the extent of the consent given.[94] Further, the genetic information can only be disseminated after further consent has been received if such consent had not been given when the genetic information was first obtained.[95] Finally, consent is deemed valid for one year or unless otherwise provided for by law.[96]

The GPA unambiguously lays out a rule for the level of consent required for the collection and use of genetic information; however the definition of "genetic information" itself and whether it applies to bloodspots was a key point in both parties' arguments in *Bearder*. The plaintiffs suggested that insisting that the rule does not apply to newborn bloodspots would render the law entirely ineffective.[97] It would essentially mean that so long as the genetic information is held in tissue form when it is transferred for research, it does not count as genetic information even if it is later examined for DNA or RNA.[98] Accordingly, the plaintiffs argued that the biological samples retained by the MDH constitute genetic information under the definition in the Minnesota statute.[99] Since the purpose for warehousing

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91 *See id.* at 10.

92 *See id.*

93 *See* MINN. STAT. § 13.386 (2006).

94 "Unless otherwise expressly provided by law, genetic information about an individual: (1) may be collected by a government entity. . .or any other person only with the written informed consent of the individual; (2) may be used only for purposes to which the individual has given written informed consent; (3) may be stored only for a period of time to which the individual has given written informed consent; and (4) may be disseminated only: (i) with the individual's written informed consent; or (ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such consent is valid for one year or for a lesser period specified in the consent." *Id.*

95 *See id.*

96 *See id.*

97 *See* Plaintiffs' Memorandum of Law, *supra* note 87, at 25.

98 *See* MINN. STAT. § 13.386 (2011).

99 *See* Plaintiffs' Memorandum of Law, *supra* note 87, at 21; *see also* "Subdivision 1. Definition. (a) 'Genetic information' means information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of: (1) the individual's biological information or specimen; or (2) the biological information or specimen of a person to whom the individual is related. (b) 'Genetic information' also means medical or biological information collected from an individual about a

the blood specimens can only be to extract further genetic information from them, although the bloodspots are not specifically DNA or RNA information, they are essentially latent genetic information.[100] Furthermore, unlike the "Common Rule,"[101] the plaintiffs noted that the GPA does not include any expectations for de-coded samples.[102]

The district court judge disagreed with the plaintiffs, and the Minnesota Court of Appeals affirmed the decision to grant summary judgment.[103] Yet, the district court seemingly sidestepped any question of whether there is a constitutional violation in the continued control over these specimens.[104] The court simply declared that these specimens were "biological samples, not genetic information as defined in the GPA."[105] As a solution, the district court merely informed the parents that if they were so uncomfortable with the samples being on file, they could avail themselves of the law and have the samples destroyed.[106] However, this decision does not address the potentially legitimate reasons, explained above, why an individual might wish to have those blood samples remain on file.[107] For example, individuals may wish that these bloodspots remain on file in the event of a missing person's case or the development of an illness.[108]

Further, despite the fact that they have already determined that the GPA does not apply, both the district court and circuit court cling to the idea that since the NBS statute requires that parents be informed that bloodspots "may" be retained, this automatically constitutes "express" statutory permission to store and disseminate the information under the GPA.[109] As established above, the GPA allows for the lawmakers of Minnesota to write around the consent requirement by explicitly stating in the law that the genetic information will be retained and possibly disseminated.[110] In so doing, Minnesota avoids the need for obtaining further consent from parents. The court rested on the idea that the NBS statute's indication that the bloodspots "may" be retained waives the requirement of informed consent; however, this required a loose interpretation of the GPA. The

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particular genetic condition that is or might be used to provide medical care to that individual or the individual's family members." MINN. STAT. § 13.386 (1) (2011).

100 *See* Plaintiffs' Memorandum of Law, *supra* note 87, at 23.

101 *See infra* discussion Part II.D.

102 *See id.*

103 *See* Trial Order, Bearder v. State, 788 N.W.2d 144 (Minn. Ct. App. 2010) (No. 09-5615), 2009 WL 5454446; *see also* Bearder v. State, 788 N.W.2d 144 (Minn. Ct. App. 2010).

104 *See* Trial Order, *supra* note 103.

105 *Id.*

106 *See id.* at *2.

107 *See* Kharaboyan, Avard & Knoppers, *supra* note 8.

108 *See id.*

109 *See* Trial Order, *supra* note 103; *see also Bearder*, 788 N.W.2d 144.

110 *See* MINN. STAT. § 13.386 ("*unless otherwise expressly provided by law* [emphasis added] genetic information . . . (3) may be stored . . . (4) may be disseminated. . . .") (referring to the fact that the law requires informed consent for the use, dissemination, and storage of the genetic information unless an exception is explicitly written into the law).

GPA's language and structure suggests that it was created to ensure that the government does not use, store, or disseminate its citizens' genetic information without placing them on express notice of the possibility. Granted, the word "may" could conceivably put a shrewd citizen on notice that the blood spots could be retained. However, it does not have any impact on an express notice that the bloodspots would be given out to the first researcher who recognizes the NBS bloodspot bank's value.

C. A Roadblock to Success in the Courts

1. The "Tissue Ownership" Cases

Bearder is currently the only case of its kind directly addressing the NBS program's storage and usage policies.[111] However, since there is a NBS program in every state and the District of Columbia, and research suggests that there are more similarities among the programs than differences,[112] it is unlikely that *Bearder* will be the last of its kind. Further, the arguments made by the plaintiffs in these future cases will likely be similar to the arguments made in *Bearder.* There is a line of precedent, known as the "tissue ownership" cases, not mentioned by the district court in *Bearder* that is likely to inform the decisions made by judges in these cases. These cases can be traced back to *Moore v. Board of Regents*,[113] and although there is some opportunity to differentiate this line of precedent from the NBS program situation, they provide a platform on which a more solid opinion can be built.[114]

Mr. Moore suffered from hairy cell leukemia,[115] and his doctor recommended that he have his spleen excised.[116] The treatment was successful;

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[111] The only exception is a case filed in Texas which quickly settled. *See* Complaint, Beleno v. Tex. Dep't of State Health Serv., No. 09-00188 (W.D. Tex. 2009).

[112] *See generally* Therrell, *supra* note 6.

[113] *See* Moore v. Regents of the Univ. of Cal., 793 P.2d. 479 (Cal. 1990).

[114] The plaintiffs actually discussed *Moore* in their brief so it is evident that the district court would have been aware of the case and presumably the line of cases associated with it. This author finds it interesting that neither the district court nor the appellate court discussed this line of precedent in its opinion when the ammunition against the plaintiff's argument was so willingly provided.

[115] Hairy cell leukemia is a rare form of leukemia (blood cancer) which results in a patient's bone marrow producing high numbers of abnormal B-cells (a white blood cell that fights infection). The "hairy" appearance of these abnormal cells is what gives this form of leukemia its name. Hairy cell leukemia has a higher rate of incidence in men than women and is more commonly found in middle aged and older adults. It is considered a chronic disease because there is no cure and never completely disappears, although remission can last for years. *See* Mayo Clinic Staff, *Definition*, THE MAYO CLINIC, http://www.mayoclinic.com/health/hairy-cell-leukemia/DS00673 (last visited Jan. 17 2011). Although hairy cell leukemia may present without any symptoms, some of the more common symptoms are a feeling of fullness in the abdomen (caused by an enlarged spleen), fatigue, easy bruising, recurring infections, weakness, and weight loss. *See* Mayo Clinic Staff, *Symptoms*, THE MAYO CLINIC, http://www.mayoclinic.com/health/hairy-cell-leukemia/DS00673/DSECTION=symptoms (last visited Jan. 17, 2011). Common treatment for the disease includes chemotherapy, immunotherapy (makes the abnormal blood cells more recognizable to the immune system) and the removal of the spleen called a splenectomy. *See* Mayo Clinic Staff, *Treatments and Drugs*, THE MAYO CLINIC, http://www.mayoclinic.com/health/hairy-cell-leukemia/DS00673/DSECTION=treatments-and-drugs

however, Moore's physician continually recommended that he return for follow-up care and provide additional tissue samples under the guise of continued monitoring of his health.[117] What actually occurred was that Moore's treating physician and another doctor had discovered that the cells from his spleen could be used to develop a valuable cell line, which they eventually patented while employed at the University of California Los Angeles ("UCLA").[118] When Moore returned for his "check ups," his doctors were actually collecting samples to study and utilize.[119] Upon discovery of this scheme and the successful cellular line, Moore unsuccessfully sued UCLA and the researchers for a share of the profits derived from his cells.

Since *Moore*, there have been several other cases dealing with the dispute over tissue ownership and informed consent in the collection of these tissue samples. For instance, in *Greenberg v. Miami Children's Hospital*, the plaintiffs, parents with children suffering from Canavan disease,[120] asked the defendant, Dr. Matalon, to isolate the genetic mutation and develop a test to detect it.[121] The plaintiffs worked with Dr. Matalon, raising funds, finding families to participate in the study, and contributing their physical tissue.[122] The plaintiffs believed that when the gene was discovered and the test was created, it would be widely available to anyone who felt they were at risk for passing on the mutation; however, when the research was complete, Dr. Matalon and Miami Children's Hospital patented the gene and began to enforce the patent and collect royalties.[123] Upon discovering that the patent was being enforced, the plaintiffs unsuccessfully sued.[124]

(last visited Jan. 17 2011).

116 *See Moore*, 793 P.2d. 479.

117 *See id.* at 481.

118 *See id.* at 482.

119 Moore v. Regents of the Univ. of Cal., 793 P.2d. 479, 482 (Cal. 1990).

120 Canavan disease is a genetic cerebral degenerative disease in which the white matter of the brain degenerates into spongy tissue caused by a mutation in the gene for a particular enzyme, aspartoacylase, which is imperative for the formation of Myelin (the fatty covering that insolates the nerve fibers in the brain). Canavan disease is most frequent among Ashkenazi Jews from eastern Poland, Lithuania and Western Russia as well as Saudi Arabians. In order to have a child with the disease, both parents must be carriers of the gene; if this is so, the chances of each individual pregnancy resulting in a child with Canavan is 25%. Symptoms of the disease appear in early infancy and progress rapidly. They include, among others, mental retardation, loss of motor skills, abnormal muscle tone, paralysis, blindness and/or hearing loss. Characteristically, children with the disease are described as quiet and apathetic. Death usually occurs before the age of 4 but some children survive into their teens and twenties. At this time there is no cure. *See* Office of Communications and Public Liaison, *NINDS Canavan Disease Information Page*, NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, http://www.ninds.nih.gov/disorders/canavan/canavan.htm (last visited Jan. 17, 2011).

121 *See* Greenberg v. Miami Children's Hosp. Research Inst. Inc., 264 F.Supp.2d. 1064 (S.D. Fla. 2003).

122 *See id.* at 1067.

123 *See id.*

124 *See id.*

This line of precedent has produced an uncomfortable result upon which the NBS cases can easily be decided. This is the idea that when a patient or a research subject gives his or her informed consent for an original purpose,[125] after that consent has been granted and the original purpose satisfied, further consent is not needed to use the tissue in a manner beyond the original purpose.[126] This holding retains the opportunity for the government in NBS cases to argue that since parents consented in some form to the blood tests, the government no longer has to obtain further consent to allow research to be performed on the leftover blood.

i. Informed Consent in the Tissue Ownership Cases

One of the causes of action in *Moore* was under the theory of informed consent.[127] In a doctor-patient situation, a patient is required to give informed consent. This means the patient must be provided with all the information necessary to make a full and informed decision about his or her treatment, including the identification of the doctor who will be performing the treatment.[128] The primary motive for requiring informed consent is to protect physicians from future liability in battery[129] malpractice cases for failing to properly warn patients of the possible risks of treatment or for performing a treatment when an equally viable and perhaps less harmful option was available.[130]

Moore based his informed consent theory on the argument that the doctor's research interest in Moore's cells constituted a conflict of interest between that of the doctor's interest to retrieve the spleen for a potentially lucrative line of research and Moore's interest in keeping his spleen. This conflict of interest, had Moore been aware of it, may have prompted Moore to seek out another physician for treatment.[131] Moore argued that part of the informed consent for his procedure should have been the doctor's financial motives, since a major part of informed consent in doctor-patient[132] circumstances is the disclosure to the patient of all information that might reasonably affect his decision.[133]

The judge in *Moore*, however, determined that regardless of the doctor's potential ulterior financial motives, when Moore gave his consent to have his spleen removed by his doctor, he was fully informed as to the physical risks of the

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125 In *Moore*, this would be treatment; in *Greenberg*, the original purpose was to find a test for Canavan's Disease.

126 In *Moore*, this would be the creation of a valuable cell line; in *Greenberg*, it would be the patenting of the test and monetary benefit from that patent.

127 *See* Moore v. Regents of the Univ. of Cal., 793 P.2d. 479 (Cal. 1990).

128 *See* Lars Noah, *Informed Consent and the Elusive Dichotomy between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 363 (2002).

129 "An intentional and offensive touching of another without lawful justification." BLACK'S LAW DICTIONARY 63 (9th ed. 2009).

130 *See* Noah, *supra* note 128, at 366.

131 *See id.*

132 As opposed to researcher-subject.

133 *See* Moore v. Regents of the Univ. of Cal., 793 P.2d. 479, 483 (Cal. 1990).

surgery.[134] Although the doctor's motives for performing the surgery were not entirely pure, there was no indication that the removal of Moore's spleen was unnecessary.[135] One author argues that this is essentially a failure to "distinguish between Moore as a patient and Moore as a research subject"[136] and the consent Moore gave should not have been perceived as Moore consenting to his tissue being used in the development of the cell line.[137] In Moore's case, as the court indicates, it is unlikely that a different physician would have recommended not removing the spleen, and Moore's knowledge of his doctor's potential conflict may only have slowed down a surgery that was inevitably going to occur, so the conflict of interest was perhaps not material.[138] Once the spleen was removed, the utilization of that tissue in the doctor's research would not cause further physical harm to Moore, and thus no further consent was required.

Unlike in *Moore,* the *Greenberg* plaintiffs were consenting to the initial research, and this consent was likely informed consent as considered under the Common Rule.[139] The plaintiffs were not arguing that they did not consent to the research at all; rather, they argued that had they known and understood that the researcher intended to profit from the creation of the test for Canavan disease, they would not have consented to participating in the research.[140] This, they claimed, violated the Miami Children's Hospital's informed consent framework, which follows the Common Rule[141] and requires a specific level of consent for any research considered human subjects research as defined by the Minnesota statute.[142] Moreover, the Common Rule requires that research participants are asked for and have given their informed consent "under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."[143] Informed consent under this framework includes a statement describing the study including its purpose and procedures, an explanation of reasonably foreseeable risks, a description of the benefits the subject might

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134 *See id.*

135 *See id.*

136 Gail Javitt, *Why Not Take All of Me? Reflections on the Immortal Life of Henrietta Lacks and the Status of Participants in Research Using Human Specimens*, 11 MINN. J.L. SCI. & TECH. 713, 738 (2010).

137 *See id.*

138 *See* Moore v. Regents of the Univ. of Cal., 793 P.2d. 479 (Cal. 1990).

139 *See* 45 C.F.R. § 46.116 (2005).

140 *See* Greenberg v. Miami Children's Hosp. Research Inst. Inc., 264 F.Supp.2d. 1064 (S.D. Fla. 2003).

141 The Miami Children's Hospital's (the defendants in *Greenberg*) website indicates that it follows the consent requirements formed under the Federal Drug Administration's procedure for informed consent. *See* Miami Children's Hospital, *MCH Research Institute Participants – Human Subjects Protection Program*, http://www.mch.com/page/EN/2586/MCH-Research-Institute/Participants---Human-Subjects-Protection-Program.aspx (last visited Jan. 18, 2011). These requirements for consent are essentially identical to the common law.

142 *See* 45 C.F.R. § 46.116.

143 *Id.*

reasonably expect to receive from the study and a description of the extent to which the subject's records will be kept confidential.[144]

Even though the research participants in *Greenberg* may have been provided the aforementioned information required for informed consent under the Common Rule, not informing the participants that he planned to use the test to create a patent and benefit from it financially was a coercive effort on the part of the researcher to ensure that he received the research grant rather than be limited by the plaintiff's interests or possibly lose the project to another researcher.[145] A second round of consent was deemed unnecessary since the research participants were considered informed when they "donated" their material. Further, since the primary function of the research for which informed consent was granted had already been met,[146] the researcher now had the freedom to do with the research what he wished, despite an indication that the research would never have existed had the participants known at the time that the researcher was planning to profit from the test that was created.[147]

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[144] *See id.*

("(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject: (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (2) A description of any reasonably foreseeable risks or discomforts to the subject; (3) A description of any benefits to the subject or to others which may reasonably be expected from the research; (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject: (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable; (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; (3) Any additional costs to the subject that may result from participation in the research; (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and (6) The approximate number of subjects involved in the study.")

[145] *See Greenberg*, 264 F.Supp.2d., at 1068.

[146] A fully functioning test for Canavan's Disease had been developed.

[147] *See* Greenberg v. Miami Children's Hosp. Research Inst. Inc., 264 F.Supp.2d. 1064 (S.D. Fla. 2003).

In *Moore* and *Greenberg*, the donor was deemed to have given consent, even informed consent, to any and all usage of the tissue from the moment the consent was given to the initial usage.[148] In Moore's case, it was the consent he gave to having his spleen excised for a medically valid reason, and in *Greenberg*, it was the parents' consent given to the researcher to perform the research.[149] Despite the fact that there was an indication that both Moore and the parents in *Greenberg* might not have consented had they known at the time that their tissue was going to be used for reasons to which they might object, the judges in these cases seem to justify their decision by stating that they do not wish to cool the fervor of medical research and progress by opening researchers up to litigation for failure to obtain adequate consent.[150]

B. Tissue Ownership Cases, and Their Relation to the NBS Cases

1. Utilizing the Cases in Favor of the State

Moore, *Greenberg*, and the other cases in this line create strong precedent for the principle that when tissue samples are removed from the body or freely donated for any one purpose with the required level of consent granted by the patient or research participant, this consent transfers to all uses of that tissue once the original use for the tissue has been satisfied. The major justification in these cases is the continued protection of the scientific researcher and his scientific pursuits over the protection of the subject. The fear expressed is that increasing demands on researchers to ensure that the subjects' consent for the continued use of their cells would be too burdensome or result in excessive litigation and consequently cool scientific inquiry. The courts apply a "pro-research" lens and loosely read the consent rules to allow the continued use of tissue samples without additional hurdles.

Bearder is also a "pro-research" case. The court, by not enforcing the GPA or insisting on stricter consent rules, gave the MDH as much leeway as possible to continue collecting and disseminating valuable bloodspots.[151] A decision in favor of the research subjects could have tragic consequences for the scientific community and their ability to access the treasure trove of data contained within the stored bloodspots. For example, *Beleno v. State Health Services*, a case filed within months of *Bearder*, concerned the NBS program in Texas.[152] The lawsuit settled and part of the agreement entailed the destruction of 5.3 million blood samples, a devastating blow for any researcher.[153] It is understandable that judges

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[148] *See* Moore v. Regents of the Univ. of Cal., 793 P.2d. 479 (Cal. 1990); *see also Greenberg*, 264 F.Supp.2d. 1064.

[149] *See id.*

[150] *See id. See also* Javitt, *supra* note 136.

[151] *See* Bearder v. State, 788 N.W.2d 144 (Minn. Ct. App. 2010).

[152] *See* Complaint, Beleno v. Tex. Dep't of State Health Servs., No: 09-00188 (W.D. Tex. 2009).

[153] *See* Jay Root, *Texas Officials Agree to Destroy Babies' Blood Samples After Settling Lawsuit,*

are reluctant to place limits that might cause the loss of millions of unique scientific data points, whether they are physically destroyed or permanently sealed off from the scientific community.

The tissue dispute cases are a tempting foundation of support for NBS program cases and one that is easily argued once an understanding of basic anatomy is established. A bodily tissue is "an aggregation of morphologically similar cells and associated intercellular matter acting together to perform specific functions in the body."[154] Although most often it is referred to as body fluid, blood is anatomically considered a connective tissue.[155] Bloodspots therefore are tissue samples.[156] One could argue that for the sake of research, the practice of allowing the use of bloodspots without more in-depth consent should be allowed to continue unimpeded. Further, since parents can always ask for the tissue sample to be destroyed, those parents who do not choose to have the sample destroyed are indicating that they do not object to the samples being held and used in potentially lifesaving and scientifically significant research.

C. Differentiating the NBS Cases from the Tissue Ownership Cases

The line of precedent established by *Moore* and its progeny will be a difficult one to overcome when later NBS cases reach the courts. However it is not impossible to find a key variable between the two types of cases that may allow for an argument differentiating the two. One possible area of differentiation involves the various types of consent given in the tissue ownership cases as opposed to the types of consent given in the NBS cases. [157]

THE DALLAS NEWS, (Dec. 23, 2009, 2:32 AM), http://www.dallasnews.com/sharedcontent/dws/news/texassouthwest/stories/DN-blood_23tex.ART.State.Edition1.4ba9636.html.

154 TISSUE, THE AMERICAN HERITAGE STEDMAN'S MEDICAL DICTIONARY, http://dictionary.reference.com/browse/tissue (last visited Jan. 18, 2011).

155 *See* NEIL A. CAMPBELL & JANE B. REECE, BIOLOGY 823 (Peterson Education Inc., 7th ed. 2005) ("The major types of connective tissue in vertebrates are loose connective tissue, adipose tissue, fibrous connective tissue, cartilage, bone and blood.")

156 *See id.* at 824 ("Although blood functions differently from other connective tissues, it does meet the criterion of having an extensive extracellular matrix. In this case, the matrix is a liquid called plasma, consisting of water, salts, and a variety of proteins. Suspended in the plasma are two classes of blood cells, erythrocytes (red blood cells) and leukocytes (white blood cells), and cell fragments called platelets. Red cells carry oxygen; white cells function in defense against viruses, bacteria and other invaders; and platelets aid in blood clotting. The liquid matrix enables rapid transport of blood cells, nutrients, and wastes through the body.").

157 There is another group of arguments made in the tissue ownership cases surrounding property rights to the tissue sample. Both the plaintiffs in *Moore* and *Greenberg* argued on grounds of conversion: that the defendants wrongfully converted the property right the plaintiffs had in their tissue. The court in *Moore* dismissed this claim since "Moore clearly did not expect to retain possession of his cells following their removal, to sue their conversion he must have retained an ownership interest in them." Moore v. Regents of the Univ. of Cal., 793 P.2d. 479, 488-49 (Cal. 1990). In *Greenberg*, the court dismissed the conversion of property argument by stating that the plaintiffs were "donors" and not "objects of human experimentation" and thus no longer retained property rights in the tissue they donated once they relinquished control of the tissue. Greenberg v. Miami Children's Hosp. Research Inst. Inc., 264 F.Supp.2d. 1064, 1071 (S.D. Fla. 2003). The difference between the NBS cases and the tissue ownership cases is that the NBS programs involve the government taking control over the tissue samples. It might be interesting to explore whether government control over the samples changes any of

It might be argued that the holdings in *Moore* and *Greenberg* turn on the requirement that active informed consent was taken from the patients and research subjects whereas in the majority of NBS programs,[158] what occurs is, at best, passive or implied consent. For example, in *Bearder* the non-action by the parents surrounding the decision to destroy the samples was considered to be implied consent to continue to store the samples.[159] However, implied consent is not informed consent. The plaintiffs in both *Moore* and *Greenberg* presumably were provided the requisite level of information required from a patient about either the procedure they were about to undergo or the research that was going to be performed on their tissue samples.[160] The issue only arose after the original use of the tissue had been completed and the researcher wanted to do more with the sample than they had originally indicated.

At the very least, the plaintiffs in *Moore* and *Greenberg* had an opportunity to examine the medical possibilities and consequences of turning over their tissue to the control of another.[161] This is different from the environment surrounding the taking of a newborn's blood sample—the explanation of the possibility of dissent and an opportunity to ask questions occurs at a time where most parents' minds are occupied with other worries. What the parents were likely to focus on, if they were told anything at all, was that this test would help the doctors identify anything that might be wrong with the baby; that it is fast, easy, and highly non-invasive; and that they have the right to opt-out of it. Under the definition of informed consent in the Common Rule, this situation and this information hardly allow time for adequate consideration of all the risks and possibilities concerning the blood test.[162]

CONCLUSION: EXPANDING BEYOND THE COURTS

With fifty-one NBS programs in the United States, half of which are retaining blood spots for longer than two years,[163] it is highly unlikely that *Bearder* will be the last case of its kind. It remains to be seen if the precedent set by *Moore* and *Greenberg* will be used by the courts in making decisions in favor of the state; however, even if this line of precedent does not become the lynchpin of the debate, it is evident from *Bearder*'s pro-research rhetoric[164] that the conflict between

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the arguments or if it produces new ones. It also might be interesting to compare NBS programs to government programs like forensic DNA data banks. However this discussion is beyond the scope of this note.

158 *See supra* text accompanying note 56.

159 *See* Bearder v. State, 788 N.W.2d 144 (Minn. Ct. App. 2010). Assuming that the parents were made aware that they had the opportunity to opt-out of the testing program or have their child's samples destroyed after testing was complete.

160 *See supra* text accompanying note 125.

161 *See generally Moore*, 793 P.2d. 479; *Greenberg*, 264 F.Supp.2d. 1064.

162 *See supra* text accompanying note 125.

163 *See* Therrell, *supra* note 6.

164 *See* Trial Order, *supra* note 103. *See also Bearder*, 788 N.W.2d 144.

providing protections for the citizen and promoting scientific research will remain a concern. The problem with solving this debate in court is that while courts are trying to protect the continuation of research by allowing the practice of accessing bloodspots to continue without change, they are at the same time undermining the original purpose of these bloodspots, since the inevitable result of the attention these lawsuits will receive will be fearful parents pulling their children from the NBS programs.

With *Bearder* indicating that there are more lawsuits to come and, with them, more media attention on the issue, it is time for an update of a system that has been in place since Robert Guthrie invented the Guthrie Card in the 1960's. Although the courts might be swayed to support parents in their lawsuits, the most likely entity for change will be the state and federal legislatures. Key policy changes can be put into place that will allow parents to feel secure in their decision to allow their child to get the blood tests they need and remain on file for researchers to examine. The first step is to create a format for active and informed consent.[165] The consent process should clearly indicate whether the state intends to continue to store the newborn blood spot, for how long, and for what purposes. Parents should understand the potential advantages they would be giving up by choosing not to store their baby's blood.[166] The consent process should also explain the possibility that the bloodspots will be used in research, as well as indicate clearly whether or not the consent being given includes blanket consent to participate in such research.

Implementing a consent process like the one suggested above will ensure greater transparency in the NBS programs, providing parents with the peace of mind that comes with understanding where their child's biological information will be stored and in what instances it will be disseminated. Individuals are generally willing to submit their biological information to biobanks and are more likely to submit when they feel they have some control over the decision.[167] This transparency and its subsequent peace of mind will allow the NBS programs to continue smoothly to protect the lives of newborns while still allowing researchers access to the wealth of knowledge available in the bloodspot biobanks.

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[165] For researchers, one consequence of active and informed consent is that there is going to be a population of people who opt-out of the blood testing after being fully informed or who will request the blood spots be destroyed after the tests have been performed. Researchers will bemoan that this population will be lost from their data set. However if the alternative is a law suit that results in the destruction of the entire data set, this author feels that the objection will quickly become moot.

[166] For example: having a pristine DNA sample for future identifications or to examine in the event of Sudden Infant Death Syndrome. *See* Kharaboyan, Avard, & Knoppers, *supra* note 8.

[167] *See* Kaufman, Murphy-Bollinger, Scott, & Hudson, *supra* note 48.