

# Newborn DNA Storage Raises Serious Privacy Concerns

Jeremy Gruber<sup>1</sup>

<sup>1</sup>Affiliation not available

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JEREMY GRUBER

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CORRESPONDENCE:  
[jeeg@concentric.net](mailto:jeeg@concentric.net)

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Before they are even a week old, ninety-eight percent of the 4.3 million babies born annually in the United States have a small sample of blood taken from their heels. These newborn bloodspots (NBS) are then screened for a variety of inherited conditions and are often later stored in state-operated databases. Newborn screening itself is an important public health program and some have described these residual sample “biobanks” in equally positive terms. Although there are concrete benefits of newborn testing, there are also troubling consent and privacy issues raised by the screening, storage and use of the samples.

Newborn screening began in the United States as a series of state level pilot programs in the 1960s to test for PKU, a rare genetic condition that is easily treatable if caught early. The success of these early programs led to rapid adoption of newborn screening among all states in the US and the number of conditions screened for has grown progressively since with additional funding at the Federal level. Because of the singular history of newborn screening, it remains the only widespread health testing in the US conducted not by an individual’s doctor, hospital, or health care provider but by individual state departments of public health. This singular history can also account for a wide disparity in state law and policy with regards to parental consent, sample storage and use.

If there is one commonality among state newborn screening practices, it’s the complete lack of transparency of the entire process, from screening to sample storage and sample use. Indeed, not only do most parents never realize they have “consented” to storage of their children’s biological material, they fail to understand that the actual state government (as opposed to the hospital) is the entity in possession of this sample. Several studies have shown that the vast majority of parents want to be actively informed of screening even if they support the practice, moreover they want the choice as to whether the state should maintain their child’s sample after screening is completed and most oppose the long term or indefinite storage of such samples.

Even though parents want informed consent to store and use the samples, most states do not have clearly articulated policies about screening and consent for the storage and use of samples, do not effectively communicate these policies to parents and do not offer parents a truly informed choice about whether to participate in storage procedures. In fact, almost all states operate on an opt-out model which requires parents to actively express explicit refusal. Such a model assumes, almost always incorrectly, that parents have been well informed of their state’s screening programs and their consent options. At last count, 18 states keep newborn DNA samples 10 years to indefinitely. In 2009, the federal government awarded a contract to the American College of Medical Genetics (ACMG) to develop a National Newborn Screening Translational Research Network to, among other things, create a physical or virtual repository of newborn DNA “stored by state newborn screening programs and

other resources.” Currently four states participate in a virtual repository, or as the URL notes, a “tissuelocator”: California, Iowa, Michigan and New York. In addition, 18 states have not addressed the retention and use of newborn DNA. Four states claim the child’s DNA as state government property. Only three states require parents to be told they can opt-out of the DNA storage and use program, and only five states actually let parents request the destruction of the stored bloodspots.

How many parents, having just had a baby and still in the hospital truly understand what the state may or may not be telling them? The reality, of course, is that many parents are not well informed about screening programs or consent, due to inopportune methods and timing of information dissemination and the lack of adequate training for medical professionals responsible for communicating the information. Parents, understandably, want to be actively involved in decision-making regarding their children’s personal health information. Consent not only allows parents to make choices about their child’s genetic privacy but is crucial to promoting greater governmental transparency. Such transparency is especially important because newborn screening and storage is often exempted from state genetic privacy laws. Researchers and administrators working with these samples know very well how alarming newborn blood spot biobanking can sound to most people, which explains why many of these clinicians, researchers and state labs would prefer newborn screening practices keep a low profile. However, public health officials’ desire to avoid controversy must be balanced against parental interest in being informed about the storage and use of their children’s bloodspots.

The concern of parents that states retain their children’s biological information is heightened because storage procedures and security at these state facilities are arcane and we still have few laws that truly protect the privacy of genetic information. Some high-profile DNA databanks have run into problems recently. A laptop was stolen containing personal information of participants in the world’s largest stem cell bank, the Cord Blood Registry; New Zealand’s national DNA database investigated a staff member’s inappropriate disclosure of information from the database; and a thief made off with an NIH laptop holding the personal and medical information of 2,500 research participants. NIH also decided in 2009 to stop making subjects’ genomic data publicly available online, after researchers at Arizona’s Translational Genomics Research Institute demonstrated how to identify individual donors within large collections of DNA profiles. A few years earlier, NIH Alzheimer’s researcher Trey Sunderland was revealed to have secretly supplied the spinal fluid samples and clinical data of over 500 research participants to Pfizer in return for hundreds of thousands of dollars.

In the past few years, parents in both Texas and Minnesota took their state health department to court on the grounds that the agency violated their child’s privacy by failing to acquire consent from the parents before storing samples and making them available to researchers. The Minnesota lawsuit (*Bearder v. Minnesota*) was dismissed, but in the Texas case (*Beleno v. Tex. Dept. of State Health Servs.*) the health department agreed to new rules for consent and transparency. Internal memos in the Texas case had indicated that when the agency was preparing to start making their store of newborn blood spots available to researchers in 2003, officials acknowledged that parents “never consented for blood spots to be used for research,” but decided to sidestep the issue. When the agency contracted with Texas A&M to warehouse the rapidly growing collection, DSHS specifically asked the university not to publicize the partnership. “This makes me nervous,” one official wrote. “A press release would most likely only generate negative publicity.” Word got out eventually, though, and investigative pieces published in the Texas Tribune certainly did generate negative publicity. With the help of the Texas Civil Rights Project, a group of parents took the state to court. DSHS settled quickly, agreeing to destroy over 5 million newborn blood spot samples it had stored and made available to outside parties without parental consent.

The absence of clearly articulated and communicated consent policies is particularly problematic because of the mismatch between the promise of maintaining residual sample databases and the actual benefits generated by such storage. Around the country, researchers, public health officials and patient groups often emphasize the value that these databases represent, but the actual benefits generated are much less dramatic than their statements would suggest. In its 2005 report, the

American College of Medical Genetics (ACMG) stated that newborn screening offers the opportunity to “better [understand] disease history and characteristics” and provides hope for “earlier medical interventions” to be developed in the future. It is this hypothetical promise that has driven the expansion of such biobanks. However, according to officials that CRG contacted that are administering the screening programs in New York, Massachusetts, and North Carolina, newborn screening is mostly used to ensure that existing tests meet quality control standards, and, in certain cases, are used to formulate new screening tests. They also indicated that is the common use in other states as well. While these are certainly beneficial applications of newborn screening, they seem to fall short of the stated promises of elucidating disease characteristics and generating earlier interventions. Such practices certainly don’t require the number of samples that states are currently storing. When asked about other applications of newborn screening, none of these public health officials could offer examples of research projects that had yielded results aligned with the promises stated in the ACMG paper; a survey of the available medical literature also failed to turn up more than a handful of studies reflecting the benefits promised by the ACMG. Thus, it appears that the cost-benefit calculus of newborn screening is more complicated than one might expect.

Newborn screening is one of the few forms of genetic testing to which almost everyone is exposed. Yet parental and just general public knowledge of newborn screening and storage practices is extremely limited. The biological sciences are now charter members of the Big Data Club. With every passing year, they turn more often to big data to probe everything from the regulation of genes to the evolution of genomes. These newborn databases offer a still largely untapped resource for their machinations and there is no overall governing privacy framework to ensure individuals privacy and control over their own information. A public debate around newborn screening protections can’t happen soon enough; already states are conducting pilot programs to replace current screening protocols with whole genome sequencing which would add even more robust information to these state repositories.

Jeremy Gruber, President

Council for Responsible Genetics