

## BABY DNA - MINNESOTA

### *MDH Storing and Using Baby DNA as of 12/31/08*

NUMBER of CHILDREN	ACTION BY MINNESOTA DEPARTMENT OF HEALTH
819,282	Newborn Dried Blood Spot Samples Stored
52,519 +	Newborn Dried Blood Spots Samples Used/Shared for Research
1,567,133	Individual Child Records of Genetic Test Results Stored

### *When Test Results Database & DNA Warehouse Began*

<b>July 1, 1986</b>	MDH began retaining newborn genetic testing results (executive decision)
<b>July 1, 1997</b>	MDH began retaining newborn baby blood & DNA (executive decision)

YEAR	PARENTS REFUSE NEWBORN GENETIC TESTING
2003	2
2004	11
2005	12
2006	56
2007	72
2008	89

### *Research Projects as of 1/9/2009*

YEAR STARTED	INSTITUTION	# OF BLOOD SPECIMENS	FUNDED BY	CONSENT?	STATUS
2008	Mayo	1000	Mayo	<b>No</b>	Open
2008	Mayo	178	Mayo	<b>No</b>	Closed
2008	University of Minnesota/MDH	500	Viking's Children's Fund (UMN)	<b>No</b>	Open
2008	MDH	"In progress"	EPA Great Lakes National Program Office	Yes	Open
2007	Mayo	280	Mayo	<b>No</b>	Open
2007	PerkinElmer/ MDH	2000	PerkinElmer	<b>No</b>	Closed
2007	PerkinElmer/ MDH	2000	PerkinElmer	<b>No</b>	Closed
2007	PerkinElmer/ MDH	1900	PerkinElmer	<b>No</b>	Closed
2006	U of MN	213	Unknown	Yes	Open
2006	Univ of MN/MDH	3010	March of Dimes /Viking's Children's Fund (UMN)	<b>No</b>	Open
2006	University of Minnesota/MDH	100	Children's Cancer Research Fund	<b>No</b>	Closed
2005	Mayo	100	Mayo	<b>No</b>	Closed
2005	Mayo/MDH	40,000	Mayo	<b>No</b>	Closed
2000	University of Minnesota/MDH	20	Unknown	Yes	Closed
1997	CDC	1218	Unknown	<b>No – 812 Yes – 406</b>	Closed

Data from IRB documents and <http://www.health.state.mn.us/newbornscreening/research.html>

## **Mayo Clinic Allowed to Keep Baby DNA and Conduct Genetic Research on Children Without Parent Consent**

*Sections of the Minnesota Department of Health's 5-year \$6,985,000 contract with the Mayo Clinic (2004-2009):<sup>1</sup>*

**2.8 Quality Control and Assurance.** Contractor *may utilize* unidentified specimens or data for quality control purposes, calibration of testing methodology, methods validation and *test development*, provided that all such specimens must be unidentified in a manner that is approved by the State and that Contractor complies with the destruction requirements of Minn. Stat. §144.125 subd. 3. *[emphasis added]*

*[NOTE: Test development is research. Not only does the Mayo Clinic have a multi-million dollar contract with MDH, the Mayo Clinic also offers private supplemental newborn testing across the country. This represents a separate commercial interest for the Mayo Clinic under the heading of 'test development.']*

**2.10 Ownership, Control, Storage, and Disposal of the Dried Blood Spots.** The Contractor hereby acknowledges that all dried blood spot ("Newborn Screening" or "NBS") specimens tested pursuant to this Agreement *belong to the State*. After the completion of testing by Contractor, the NBS card with leftover deried blood will be securely kept and stored by Contractor for a period of *at least two years*, unless the parents opt to have the dried blood specimens destroyed sooner as permitted by Minn. Stat. §144.125 subd.3. The State will notify the Contractor in writing of such individual request, and Contractor shall promptly destroy the specimen. *If no request for destruction is received*, the NBS card with residual dried blood will be destroyed by Contractor in accordance with its usual and customary specimen retention and destruction policies. *[emphasis added]*

*[NOTE: Specimens are not typically discarded by the Mayo Clinic. According to a St. Paul Pioneer Press report, Mayo has a warehouse of biological specimens dating back to 1906.]*

**2.11 Use of Specimens or Data for Research.** Any request to use unidentified specimens or data *for purposes other than those listed in section 2.8* requires the written authorization of Contractor's Institutional Review Board, the State's Authorized Representative and MDH's Institutional Review Board, and any other individual consents as required by law. Requests must specify, at a minimum, how Contractor will unidentify specimens or data and how Contractor will comply with the parent's wishes for the destruction of the specimens or data. No identifiable specimens or data may be used for research without the written authorization of the State's Authorized Representative, the Institutional Review Boards of MDH and Contractor and the written consent of the subject's parent or legal guardian. *[emphasis added]*

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<sup>1</sup> The term "Contractor" in the contract means the Mayo Clinic.