

	Current Practice	After BioTrust
Primary reason for collection of DBS	Universal, mandatory newborn screening	Universal, mandatory newborn screening
Parental consent for newborn screening	No - testing is mandated by state law	No - testing is mandated by state law
Used for medical research	Yes, rarely. Research applications are limited due to storage conditions and limited awareness among researchers.	Yes, increased use expected due to improved storage conditions, technology advancements, and awareness of availability
Retention schedule	21 1/2 years; indefinite as of Oct 2008	Indefinite
Basis for retention schedule	Legal Recommendations, state statute	Governor's Commission on Genetic Privacy recommendation ; state statute
Where blood spots are stored	Department of Management and Budget document storage facility in Lansing	TechTown at Wayne State University
Financial support for storage	Newborn Screening program fees. There is a charge for each newborn screening card which goes to support the NBS program, including storage of DBS.	Fees to researchers for DBS storage and handling
Storage Conditions	Room temperature, humidity not controlled	-20°C, controlled humidity, zip lock plastic storage bags
Specimens de-identified prior to release to researcher	Yes	Yes, double de-identification
Available for parents or individuals after age 18 for directed use	Yes	Yes
Destroyed per instruction of parent or individual after age 18	Yes. A parent of a child, or the child upon reaching age 18, can contact the Newborn Screening Program to request that the remaining blood spot samples be removed from the research pool or destroyed.	Yes. A parent of a child, or the child upon reaching age 18, can contact the Newborn Screening Program to request that the remaining blood spot samples not be included in the BioTrust, or be destroyed.
Notification of potential research use of sample	Parent informed in brochure distributed by birthing hospital	A more visible public awareness campaign, parent brochure, and consent process
Active notification of researchers of the availability of DBS collection	No	Yes
MDCH Institutional Review Board (IRB) approval for each study	Yes	Yes
Scientific merit of study reviewed?	Yes, by State Epidemiologist and State Public Health Lab Director	Yes, Scientific Review Board appointed by MDCH
Community input on DBS and/or data linkage uses	Yes, through IRBs at the researcher's institution and MDCH	Yes, through the Community Values Advisory Board and IRBs at the researcher's institution and MDCH
Potential for linking to other public health databases (e.g., vital records, cancer registry, birth defects registry, etc.)	Yes. Data and DBS de-identified prior to release to researcher	Yes. Data and DBS de-identified prior to release to researcher
Tracking of research use of each DBS	No	Yes
Fees to researchers	Yes, based on Newborn Screening lab's personnel time to retrieve and ship	Yes, based on BioTrust infrastructure costs