Issue Brief

Informed Consent for Newborn Screening Research

Background

On July 22, 2011, the Federal Register published an Advanced Notice of Proposed Rule Making (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, seeking public input on an array of changes to the Federal Policy for the Protection of Human Subjects (or the Common Rule). The government had two overarching goals with respect to the revisions it was considering to the Common Rule (1) to enhance the protection of research subjects and (2) to improve the efficiency of the review process. HHS developed a summary of the proposed changes. These proposed changes would require written consent for research use of biospecimens, even those that have been stripped of identifiers. Public comments were received on ANPRM, but no additional actions have been taken by HHS.

Newborn Screening Saves Lives Reauthorization Act of 2014

On Dec. 18, 2014, the President signed the Newborn Screening Saves Lives Reauthorization Act of 2014 (Act) into law. Section 12 of the Act addresses the issue of informed consent for newborn screening research. The Act provides that "[r]esearch on newborn dried bloodspots shall be considered research carried out on human subjects meeting the definition of § 46.102(f)(2) of Title 45, Code of Federal Regulations for purposes of Federally funded research." The Act applies to newborn dried bloodspots collected 90 days after enactment and until regulatory updates to the Federal Policy for the Protection of Human Subjects are promulgated by the Secretary of Health and Human Services. For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations shall not apply. Those sections specifically allow for altering or waving informed consent requirements.

Analysis of Relevant State Laws

Examples of state definitions of newborn screening program operations:

State	Citation	Statute or Regulation Text
IA	Iowa Admin. Code r. 641-4.3(136A)	Newborn screening program operations. Residual newborn screening specimens may be used for activities, testing, and procedures directly related to the operation of the newborn screening program, including confirmatory testing, laboratory quality control assurance and improvement, calibration of equipment, evaluation, and improvement of the accuracy of newborn screening tests, and validation of equipment and screening methods, and the use of linked specimens in feasibility studies approved by the Congenital and Inherited Disorders Advisory Committee for the purpose of incorporating new tests or evaluating new test methodologies.
MN	Minn. Stat. Ann. § 144.125 (West)	Newborn screening program operations means actions, testing, and procedures directly related to the operation of the newborn screening program, limited to the following: (1) confirmatory testing; (2) laboratory quality control assurance and improvement; (3) calibration of equipment; (4) evaluating and improving the accuracy of newborn screening tests for conditions approved for screening in Minnesota; (5) validation of equipment and screening methods; (6) continuity of operations to ensure testing can continue as required by Minnesota law in the event of an emergency;

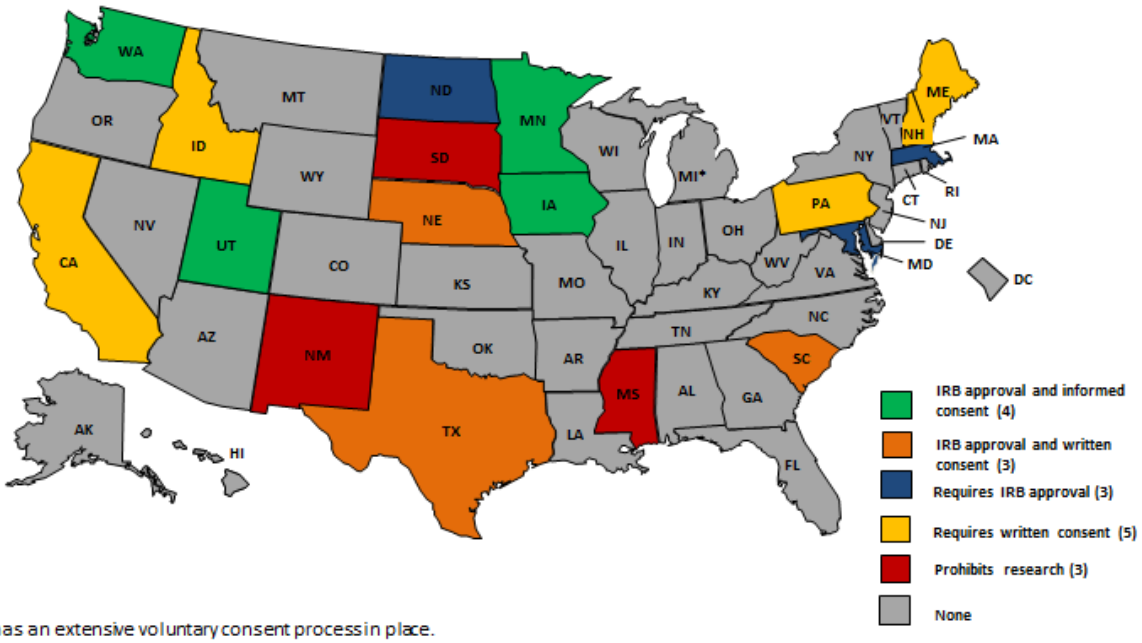
State	Citation	Statute or Regulation Text
		(7) follow-up services for the cases of heritable and congenital disorders identified by newborn screening; and (8) utilization of blood samples and test results for studies related to newborn screening, including studies used to develop new tests.
TX	Tex. Health & Safety Code Ann. § 33.018 (West)	(b) Notwithstanding other law, reports, records, and information obtained or developed by the department under this chapter may be disclosed: (6) for purposes relating to review or quality assurance of the department's newborn screening under this chapter or the department's newborn screening program services under Subchapter C, provided that no disclosure occurs outside of the department's newborn screening program; (7) for purposes related to obtaining or maintaining federal certification, including related quality assurance, for the department's laboratory, provided that no disclosure occurs outside of the department's newborn screening program; or (8) for purposes relating to improvement of the department's newborn screening under this chapter or the department's newborn screening program services under Subchapter C,[1] provided that the disclosure is approved by the commissioner or the commissioner's designee. (c) Notwithstanding other law, reports, records, and information that do not identify a child or the family of a child may be released without consent if the disclosure is for: (1) statistical purposes; (2) purposes related to obtaining or maintaining federal certification, including related review and quality assurance: (A) for the department's laboratory that require disclosure outside of the department's newborn screening program; or B) for a public or private laboratory to perform newborn screening tests that are not part of inter-laboratory exchanges required for federal certification of the department's laboratory, provided that the disclosure is approved by the commissioner or the commissioner's designee; or (3) other quality assurance purposes related to public health testing equipment and supplies, provided that the disclosure is approved by: (A) the commissioner or the commissioner's designee; and (B) an institutional review board or privacy board of the department.

Three states prohibit the use of bloodspots for anything other than test results:

State	Citation	Statute or Regulation Text
MS	Code Miss. R. 15-4-1:1.4.8	Under no circumstances will the retained specimen be used for research or purposes other than confirmation of previous test results.
NM	N.M. Admin. Code 7.30.6	Bloodspot cards shall not be disseminated after blood spot testing for any purpose unrelated to newborn screening, except to parents or guardians who may request them in writing during the retention period.
SD	S.D. Admin. R. 44:19:03:03	Upon completion of newborn screening testing, the designated laboratory is responsible for specimen destruction in a secure manner. No specimen may be used for any purpose other than the screening of newborn infants pursuant to SDCL 34-24-17.

Research on Dried Bloodspots

State Legal Requirements



* MI has an extensive voluntary consent process in place.

Four states have informed consent requirements for the release of specimens for use in research:

State	Citation	Statute or Regulation Text
IA	Iowa Admin. Code r. 641-4.3(136A)	4.3(2) *Newborn blood spot screening procedure for facilities and providers.* *e.* ***Informed consent*** *for the release of residual specimens for research use.* The department shall establish policies and procedures, including an informed consent for release of specimens for research, to allow a parent or guardian the ability to provide informed consent prior to the release of the newborn's residual newborn screening specimen for research purposes. The parent or guardian, birthing facility or attending health care provider shall submit the informed consent form to the central laboratory pursuant to established policy and procedure. The informed consent procedure shall apply to all specimens collected on or after January 1, 2016. For specimens collected prior to January 1, 2016, a parent or guardian may send a letter stating that the newborn's specimen is not to be released for research purposes.
MN	Minn. Stat. Ann. § 144.125 (West)	Consent: With the **written, informed consent** of a parent or legal guardian, the Department of Health may use blood samples and test results for public health studies or research not related to newborn screening, and upon approval by the Department of Health's Institutional Review Board, share samples and test results with external parties for public health studies or research. Research: that parents or legal guardians have a right to authorize in writing that the blood samples and test results may be used for public health studies or research. "
UT	Utah Admin. Code	(4) The Department may release blood spots for research upon the following:

State	Citation	Statute or Regulation Text
	r. R398-1	(a) The person proposing to conduct the research applies in writing to the Department for approval to perform the research. The application shall include a written protocol for the proposed research, the person's professional qualifications to perform the proposed research, and other information if needed and requested by the Department. When appropriate, the proposal will then be submitted to the Department's Internal Review Board for approval. (b) The Department shall de-identify blood spots it releases unless it obtains **informed consent** of a parent or guardian to release identifiable samples. (c) All research must be first approved by the Department's Internal Review Board.
WA	Wash. Admin. Code 246-650-050	4) Release: Dried blood spot samples and specimen information may only be released when required by state or federal law or under the following conditions: (a) A sample from a specimen and copies of associated information (patient information and testing results, if requested) may be released to: (i) A health care provider at the request of the patient or their legal representative after completing and signing a written request form approved by the department. The release form must be provided to the director of newborn screening before the request will be fulfilled. (ii) A researcher with the **written, informed consent** of the patient or their patient's legal representative as part of a research project that has been reviewed and approved by the DOH/DSHS human subjects research review board and the secretary or designee of the department of health. (iii) A named person in a legally executed subpoena following review and approval of the state attorney general.

Ten states require institutional review board approval for research:

State	Citation	Statute or Regulation Text
IA	Iowa Admin. Code r. 641-4.3(136A)	c. Research. A residual newborn screening specimen may be released for research purposes only if written consent has been received from a parent or guardian of the child, or the individual adult upon whom the screening was performed, and each of the following conditions is satisfied: (1) Investigators shall submit proposals to use residual newborn screening specimens to the center. Any intended use of the requested specimens as part of the research study must be clearly delineated in the proposal. (2) Before research can commence, proposals shall be approved by the researcher's **institutional review board**, the congenital and inherited disorders advisory committee, and the department.
MD	Md. Code Regs. 10.10.13.15	B. Research. A researcher may not use a Maryland newborn infant's blood-spot or test results for research purposes unless the: (1) Research is approved in writing by the Department's: (a) Newborn Screening Program; and (b) **Institutional Review Board**; and (2) The researcher acknowledges in writing that the researcher will return all untested blood-spots to the Department's public health laboratory within 6 months of completing the approved research
MA	105 Mass. Code Regs. 270.011	The Newborn Blood Screening Program shall maintain the confidentiality of testing results and information submitted concerning follow-up of newborn testing and shall not disclose such results or any information or patient identifiers which because of name, identifying number, mark or description can

State	Citation	Statute or Regulation Text
		be readily associated with a particular individual, except to that individual, anyone authorized in writing by that individual, authorized Department personnel, or any researcher authorized pursuant to M.G.L. c.111, § 24A for studies approved by the Department's **Institutional Review Board**.
MN	Minn. Stat. Ann. § 144.125 (West)	Consent: With the written, informed consent of a parent or legal guardian, the Department of Health may use blood samples and test results for public health studies or research not related to newborn screening, and upon approval by the Department of Health's **Institutional Review Board**, share samples and test results with external parties for public health studies or research. Research: that parents or legal guardians have a right to authorize in writing that the blood samples and test results may be used for public health studies or research.
NE	181 Neb. Admin. Code Ch. 2, 2-007	2-007.08 Use of Residual Dried Blood Spots: Residual dried blood spots may be used for public health research, further patient diagnostic testing, and public health purposes, for example, but not limited to, quality assurance and improvement of newborn screening practices. 2-007.08A Residual dried blood spots may be used for public health research only when: 1. The Chief Medical Officer and the Newborn Screening Advisory Committee or its proxy sub-committee have reviewed and approved the application for research containing but not limited to the following information: **a. The full report of the review and approval of the research by a Human Subjects Review or Institutional Review Board;** b. The qualifications of the applicant and of the principal investigator, if other than the applicant, including education, experience, prior publications, and recommendations of professional colleagues who have knowledge and experience of scientific or medical research; c. The purpose of the research project, a summary of the project, and the anticipated time of completion of the project; d. The location where the research project will be conducted and the equipment, personnel, and other resources available to the applicant to carry out the project; e. The identity of the individual or entity funding the research project, a description of the availability of funds for the research project, and any conditions on the receipt or continuation of the funding; f. The specific data or biological sample information requested and a description of the use to be made of it and, if subject-identifying data is requested, a substantiation of the need for access to the subject-identifying data; g. A description of the measures to be taken to secure the data and biological sample information and to maintain the confidentiality of such during the research project, for disposal of the data and biological sample upon completion of the study, and to assure that the results of the study will not divulge or make public, information that will disclose the identity of any individual subject; h. A written assurance/agreement that the research will be published in the public domain and communication of research results will not be restricted on the basis of the proprietary interests of commercial, private or other partners; i. A description of the process that will be used for obtaining written consent from the legally responsible parent or guardian of the individuals whose specimens will be requested; j. If contact with a subject or subject's parent or legal guardian is planned or

State	Citation	Statute or Regulation Text
		expected beyond obtaining consent as required under 181 NAC 2-007.08A1i, substantiation of the need for the contact and a description of the method to be used to obtain permission from the subject or subject's parent or legal guardian for the contact; k. Such additional information as the Department determines to be necessary to assure that release of data to the applicant is appropriate and consistent with these regulations, 181 NAC 2.
ND	N.D. Admin. Code 33-06-16-05	c. Information and testing materials may be disclosed to a person engaged in a bona fide research project concerning medical, psychological, or sociological issues provided all of the following conditions are met: (1) The research project must be sponsored by a public or private college or university; a governmental entity; a nonprofit medical, sociological, or psychological association; or the pharmaceutical industry. (2) The research project must be reviewed and approved pursuant to policies and procedures pertaining to research utilizing human subjects by the **institutional review board** or equivalent panel of the institution or entity where the research is being done or which is sponsoring the research. (3) Protected health information may not appear in any report, summation, thesis, or other document arising out of the research project. (4) Protected health information may not be provided to a person engaged in a bona fide research project until that person has submitted a written proposal explaining and justifying the need to examine such information which is satisfactory to the state health officer. The state health officer may require the research to be approved by the university of North Dakota **institutional review board**. (5) All documents or testing materials received by the researcher and all documents containing protected health information made by or on behalf of the researcher, by whatever means, including hard copies, typewritten or handwritten copies, photocopies, facsimiles, or electronic or electromagnetic recording or imaging, must be returned to the department on or before a date that the state health officer shall set. (6) The researcher shall submit a written plan explaining how all protected health information in the researcher's possession will be kept secure to the satisfaction of the state health officer who shall obtain written assurance that the plan will be implemented. (7) The researcher shall agree to provide the state health officer a copy of any report, summation, thesis, or other document arising out of the research project for departmental review of compliance with this section before providing it to the publisher. (8) The researcher shall consent in writing to the use and reproduction of the document by the department. (9) The researcher shall agree in writing to pay all costs of the state health officer or the department incurred in providing access to testing materials or other information, including copy or research services.
SC	S.C. Code Ann. Regs. 61-80	Use of Stored Specimen 1. Stored blood specimens may be released for the purposes of confidential, anonymous scientific study unless prohibited by the parent, legal guardian, or child from whom the specimen was obtained when he/she is eighteen years of age or older. 2. The Department's **Institutional Review Board** shall approve all scientific studies that use stored blood specimens before the specimens are released.

State	Citation	Statute or Regulation Text
		3. Blood specimens released for scientific study shall not contain information that may be used to determine the identity of the children from whom they were obtained by the person(s) to whom the specimens are released. The Department shall code the specimens before releasing them so that the Department can identify the children from whom the blood specimens were obtained if necessary. 4. If any such scientific study identifies genetic or other information that may benefit the children from whom the specimens were obtained, the Department may confidentially provide this information to the parents, legal guardians or children from whom the specimens were obtained when the children are eighteen years of age or older.
TX	Tex. Health & Safety Code Ann. § 33.018 (West)	b) Notwithstanding other law, reports, records, and information obtained or developed by the department under this chapter may be disclosed: 5) to public health programs of the department for public health research purposes, provided that the disclosure is approved by: (A) the commissioner or the commissioner's designee; and (B) an **institutional review board** or privacy board of the department as authorized by the federal privacy requirements adopted under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) contained in 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E; (6) for purposes relating to review or quality assurance of the department's newborn screening under this chapter or the department's newborn screening program services under Subchapter C, provided that no disclosure occurs outside of the department's newborn screening program; c-1) Notwithstanding other law, reports, records, and information that do not identify a child or the family of a child may be released for public health research purposes not described by Subsection (b)(5) if: (1) a parent, managing conservator, or guardian of the child consents to the disclosure; and (2) the disclosure is approved by: (A) an **institutional review board** or privacy board of the department; and (B) the commissioner or the commissioner's designee.
UT	Utah Admin. Code r. R398-1	(3) The Department may use residual blood spots for newborn screening quality assessment activities. (4) The Department may release blood spots for research upon the following: (a) The person proposing to conduct the research applies in writing to the Department for approval to perform the research. The application shall include a written protocol for the proposed research, the person's professional qualifications to perform the proposed research, and other information if needed and requested by the Department. When appropriate, the proposal will then be submitted to the Department's Internal Review Board for approval. (b) The Department shall de-identify blood spots it releases unless it obtains informed consent of a parent or guardian to release identifiable samples. (c) All research must be first approved by the Department's **Internal Review Board.** R398-1-16. Retention of Blood Spots. (1) The Department retains blood spots for a minimum of 90 days. (2) Prior to disposal, the Department shall de-identify and autoclave the blood spots.
WA	Wash. Admin.	4) Release: Dried blood spot samples and specimen information may only be

State	Citation	Statute or Regulation Text
	Code 246-650-050	released when required by state or federal law or under the following conditions: (a) A sample from a specimen and copies of associated information (patient information and testing results, if requested) may be released to: (i) A health care provider at the request of the patient or their legal representative after completing and signing a written request form approved by the department. The release form must be provided to the director of newborn screening before the request will be fulfilled. (ii) A researcher with the written, informed consent of the patient or their patient's legal representative as part of a research project that has been reviewed and approved by the DOH/DSHS **human subjects research review board** and the secretary or designee of the department of health. (iii) A named person in a legally executed subpoena following review and approval of the state attorney general.

Of the 12 states laws that specify that consent is required for research, 11 have an opt-in process and one has an opt-out process:

State	Citation	Statute or Regulation Text	Opt-In /Opt-Out
CA	Cal. Code Regs. tit. 17, § 6502.1	(b) Except as provided by law, such information shall not be exhibited nor disclosed in any way, in whole or in part, by any individual, group, or research team except with the written consent of the person or his/her legally authorized representative unless such data can be made available in a manner which preserves anonymity of the persons tested.	Opt-in
ID	Idaho Admin. Code r. 16.02.12.050	02. Prohibited Use of Dried Blood Specimens. Dried blood specimens may not be used for any purpose other than those described in Section 050.01 of this rule without the express written consent of the parent(s) or guardian(s) of the infant from whom the specimen was collected.	Opt-in
IA	Iowa Admin. Code r. 641-4.3(136A)	*e. Informed consent for the release of residual specimens for research use.* The department shall establish policies and procedures, including an informed consent for release of specimens for research, to allow a parent or guardian the ability to provide informed consent prior to the release of the newborn's residual newborn screening specimen for research purposes.	Opt-in
ME	Code Me. R. tit. 10-144 Ch. 283,, § 12.0	12.7 Filter paper specimens may be released for research or testing with identifiers intact with specific written request or consent of a parent/guardian; for anonymous research without consent as approved by the Department with input from the program advisory committee; or for program evaluation or planning without consent.	Opt-in
MN	Minn. Stat. Ann. § 144.125 (West)	With the written, informed consent of a parent or legal guardian, the Department of Health may use blood samples and test results for public health studies or research not related to newborn screening, and upon approval by the Department of Health's Institutional Review Board, share samples and test results with external parties for public health studies or research.	Opt-in
NE	181 Neb. Admin. Code Ch. 2, 2-	2-007.08A Residual dried blood spots may be used for public health research only when:	Opt-in

State	Citation	Statute or Regulation Text	Opt-In /Opt-Out
	007	i. A description of the process that will be used for obtaining written consent from the legally responsible parent or guardian of the individuals whose specimens will be requested. 2-007.08B Residual dried blood spots may be used for patient diagnostic testing when the ordering physician files with the laboratory a written request for specimen retrieval and a written authorization for release of the specimen signed by the parent or legal guardian.	
NH	NH ADC HE-P 3008.11	Residual DBS specimens and related records may be retrieved for other purposes only with the written authorization of a parent or guardian.	Opt-in
PA	28 Pa. Code § 28.5	(a) A health care provider, testing laboratory, the Department or any other entity involved in the newborn screening program may not release any identifying information relating to any newborn child screened in the newborn screening program to anyone other than a parent or guardian of the newborn child or the health care provider for the newborn child designated by a parent or the guardian except: (2) With the consent of the newborn child's parent or guardian. (3) With the child's consent when the child is 18 years of age or older, has graduated from high school, has married or has been pregnant.	Opt-in
SC	S.C. Code Ann. Regs. 61-80	1. Stored blood specimens may be released for the purposes of confidential, anonymous scientific study unless prohibited by the parent, legal guardian, or child from whom the specimen was obtained when he/she is eighteen years of age or older.	Opt-out
TX	Tex. Health & Safety Code Ann. § 33.0111 (West)	(a) The department shall develop a disclosure statement that clearly discloses to the parent, managing conservator, or guardian of a newborn child subjected to screening tests under Section 33.011: (2) that reports, records, and information obtained by the department under this chapter that do not identify a child or the family of a child will not be released for public health research purposes under Section 33.018(c-1) unless a parent, managing conservator, or guardian of the child consents to disclosure.	Opt-in
	Tex. Health & Safety Code Ann. § 33.0112 (West)	(a) The department shall destroy any genetic material obtained from a child under this chapter not later than the second anniversary of the date the department receives the genetic material unless a parent, managing conservator, or guardian of the child consents to disclosure under Section 33.017(c-1).	Opt-in
	Tex. Health & Safety Code Ann. § 33.018 (West)	(b) Notwithstanding other law, reports, records, and information obtained or developed by the department under this chapter may be disclosed: (2) with the consent of each identified individual or an individual authorized to consent on behalf of an identified child; (c-1) Notwithstanding other law, reports, records, and information that do not identify a child or the family of a child may be released for public health research purposes not	Opt-in

State	Citation	Statute or Regulation Text	Opt-In /Opt-Out
		described by Subsection (b)(5) if: (1) a parent, managing conservator, or guardian of the child consents to the disclosure	
UT	Utah Admin. Code r. R398-1	(4) The Department may release blood spots for research upon the following: (b) The Department shall de-identify blood spots it releases unless it obtains informed consent of a parent or guardian to release identifiable samples.	Opt-in
WA	Wash. Admin. Code 246-650-050	(4) Release: Dried blood spot samples and specimen information may only be released when required by state or federal law or under the following conditions: (i) A health care provider at the request of the patient or their legal representative after completing and signing a written request form approved by the department. (ii) A researcher with the written, informed consent of the patient or their patient's legal representative as part of a research project reviewed and approved by the DOH/DSHS human subjects research review board and the secretary or designee of the department of health.	Opt-in

Laws in three states provide for an opt-out consent process for storage of bloodspots, and laws in two states specify an opt-in process:

State	Citation	Statute or Regulation Text	Opt-In /Opt-Out
ME	Code Me. R. tit. 10-144 Ch. 283,, § 12.0	12.6 Unless the person or his/her legal authorized representative specifically prohibits such use in writing, the blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department-approved scientific researchers to improve the health of mothers and children. (Opt-out)	Opt-out
MN	Minn. Stat. Ann. § 144.125 (West)	Blood samples and test results will be used for program operations in accordance with [testing], unless the parents or legal guardians elect not to have the blood samples and test results stored, in which case the blood samples and test results will be destroyed [after testing].	Opt-out
SC	S.C. Code Ann. Regs. 61-80	4. Hospital staff or other persons who collect these specimens shall ensure that the parent's or legal guardian's storage choice is documented on the Blood Sample Storage Options form if the parent or legal guardian does not agree to have their child's blood specimen stored and potentially released for confidential, anonymous scientific study.	Opt-in
TX	25 Tex. Admin. Code § 37.56	(g) A physician (or other person attending a newborn, if no physician is present), shall ensure that: (5) the Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards form is promptly sent to the department upon being signed, and received from a parent, managing conservator, or legal guardian.	Opt-in
WA	Wash. Admin.	(2) Exception for parental request: Upon request of a parent or	Opt-out

State	Citation	Statute or Regulation Text	Opt-In /Opt-Out
	Code 246-650-050	guardian, the department will destroy the specimen/information form only after all required screening tests have been performed and if the patient's screening/clinical status related to these tests is not in question.	

Bloodspot storage requirements vary by state:

State	Citation	Statute or Regulation Text
ME	Code Me. R. tit. 10-144 Ch. 283, § 12.0	Storage conditions shall be appropriate, secure and stable and allow specimens to be retrieved if necessary.
MD	Md. Code Regs. 10.10.13.15	C. Storage. A permittee or researcher shall store a newborn infant blood-spot in a sealed, moisture-proof container at between 2° and 23°C.
NE	181 Neb. Admin. Code Ch. 2, 2-007	2-007.02F Blood Spot Storage, Use and Disposal Records: The testing laboratory must maintain for 25 years an index or catalog of the residual dried blood spots processed in the laboratory that includes the following information: 1. The serial number or unique identifier of each specimen processed; 2. The test results of each specimen processed; 3. Verification of disposal of specimens not released for research, public health, quality assurance, or diagnostic purposes. This information may be batched by test completion date so long as each serial number or unique identifier can be linked with its test completion date; 4. Date of disposal; 5. Location of disposal if other than the laboratory; 6. For specimens released for public health research, documentation as required at 181 NAC 2-007.08; and 7. Signature of the person who released, disposed of, or witnessed the disposal of the specimen; or for specimens disposed of by a contractor, written evidence that the contract for disposal of residual dried blood spots requires disposal be done in accordance with 181 NAC 2-007.02F, items 3, 4, and 5. 2-007.07 Storage of Residual Dried Blood Spots: The testing laboratory must store the residual dried blood spots for 90 days. Specimens must be refrigerated in sealed bags of low gas permeability.
NH	NH ADC HE-P 3008.10	(a) The testing laboratory shall store DBS specimens in sealed bags of low gas permeability containing a desiccant and humidity indicator at -20 degrees Celsius. (c) If the storage environment of any DBS specimen is found to have deviated from the required conditions described in (a) above, such that the stability of the specimen is likely to have been affected, the testing laboratory shall first notify the NSP and shall then destroy the DBS specimen.
SC	S.C. Code Ann. Regs. 61-80	3. The Laboratory shall store all specimens at minus 20° Centigrade and may release specimens for purposes of confidential, anonymous scientific study unless prohibited by the parents, legal guardians, or children from whom the specimens were obtained

State	Citation	Statute or Regulation Text
		when the children are eighteen years of age or older.
SD	S.D. Admin. R. 44:19:03:03	The designated laboratory shall maintain each specimen in a manner that provides security, confidentiality, and stability of temperature and humidity.
WA	Wash. Admin. Code 246-650-050	(1) Storage: The specimen/information forms shall be kept at ambient temperature in secured storage to preserve their confidentiality and prevent access by unauthorized persons.

Five state laws provide that bloodspots become property of the state or lab:

State	Citation	Statute or Regulation Text
CA	Cal. Code Regs. tit. 17 § 6505	(j) The blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department-approved scientific researchers without identifying the person or persons from whom these results were obtained, unless the person or his/her legally authorized representative specifically prohibits such use in writing.
ME	Code Me. R. tit. 10-144 Ch. 283,, § 12.0	12.6 Unless the person or his/her legal authorized representative specifically prohibits such use in writing, the blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department-approved scientific researchers to improve the health of mothers and children. Such studies are published without identifying the person or persons from whom these results were obtained.
MT	Mont. Admin. R. 37.57.321	(2) Dried blood specimens remaining after newborn screening test completion are the property of the department laboratory and will be stored for one calendar year prior to destruction.
UT	Utah Admin. Code r. R398-1	1) Blood spots become the property of the Department.
WA	Wash. Admin. Code 246-650-050	The specimen/information form submitted to the department pursuant to WAC 246-650-020 become the property of the state of Washington upon receipt by the Washington state public health laboratory. The department shall protect the privacy of newborns and their families and assure that all specimen/information forms submitted for screening are protected from inappropriate use or access.

State laws that reference retention by an academic institution:

State	Citation	Statute or Regulation Text
ND	N.D. Admin. Code 33-06-16-05	a. Information and testing materials provided to the university of North Dakota school of medicine and health sciences may be retained indefinitely or destroyed according to this subsection.

Length of time states are authorized to store dried blood spots:

State	Citation	Statute or Regulation Text
DE	Code Del. Regs. 16 4000 4107	9.3 Dried blood-spots will be retained for a period of **three years** under appropriate conditions. The stored specimens will only be used for activities to improve the screening program and/or develop new screening tests.
ID	Idaho Admin. Code r. 16.02.12.050	03. Storage of Dried Blood Specimens. Dried blood specimens may be stored at the testing facility for a period **not to exceed eighteen (18) months**. Acceptable use of stored specimens will be for re-testing the specimen in the event of a symptomatic diagnosis or death of the infant during the storage period. (7-1-10)

IL	Ill. Admin. Code tit. 77, § 661.10	e) Specimens received by the Department for newborn screening will be retained for **a minimum of two months**. If all test results obtained from a specimen are determined to be within normal range, the specimen will be retained for a **maximum of four months**. If any test result obtained from a specimen is determined to be abnormal (i.e., out of normal range), the specimen will be retained for **a maximum of six years**.
IA	Iowa Admin. Code r. 641-4.3(136A)	(1) The residual DBS specimen shall be held for **five years** in a locked area at the SHL.
MD	Md. Code Regs. 10.10.13.15	D. Retention. A permittee shall: (1) Retain a newborn infant's: (a) Gel, produced when testing for hemoglobin disorders, for at least 90 days after testing is complete; and (b) Blood-spot for **25 years** after the blood-spot is received for screening, supplemental, or diagnostic testing;
MS	Code Miss. R. 15-4-1:1.4.8	Specimen must be retained for **at least 365 days.**
MT	Mont. Admin. R. 37.57.321	Dried blood specimens remaining after newborn screening test completion are the property of the department laboratory and will be stored for **one calendar year** prior to destruction. An exception is made for screening specimens with results that are out of range which may be kept for quality improvement and new method development within the laboratory. These specimens may be stored by the laboratory for an **indefinite period of time**.
NE	Neb. Rev. Stat. § 71-519	2-007.07 Storage of Residual Dried Blood Spots: The testing laboratory must store the residual dried blood spots for **90 days**. Specimens must be refrigerated in sealed bags of low gas permeability. 2-007.10 Disposal of Residual Dried Blood Spots: Residual dried blood spots not released under 181 NAC 2-007.08 must be disposed of **within 30 days of the end of the 90-day storage time.**
NH	NH ADC HE-P 3008.10	The testing laboratory s**hall destroy DBS specimens 6 months after the collection date**, in a manner consistent with applicable federal requirements relating to the disposal of human blood and body fluids per OSHA regulations 29 CFR 1910.1030.
NM	N.M. Admin. Code 7.30.6	The newborn screening program of the department of health or contracted laboratory may store the blood samples of newborns collected for the screening of genetic disorders for **up to one year**. After that time, the blood samples shall be destroyed.
ND	N.D. Admin. Code 33-06-16-05	2. Retention and destruction of information and testing materials. a. Information and testing materials provided to the university of North Dakota school of medicine and health sciences may be retained indefinitely or destroyed according to this subsection. b. Information and testing materials may be destroyed by any available means that preserves individual confidentiality and, for the testing materials, complies with any applicable standards for destruction of human blood samples. c. Information and testing materials may be destroyed based upon the following schedule: (1) Information and testing materials created **less than ten years** before the present date may be destroyed only with the state health officer's prior written approval. (2) **After ten years**, information and testing materials may be destroyed without prior approval.

OH	Ohio Admin. Code 3701-55-03	D) Keep all newborn screening specimens and the demographic forms associated with each specimen for **not less than two years** from the date of the bureau's initial receipt of each specimen.
OR	Or. Admin. R. 333-025-0155	The Oregon Health Authority may retain the blood samples of newborns collected for the control of metabolic diseases, as provided in ORS 433.285, **for up to one year**.
TX	Tex. Health & Safety Code Ann. § 33.0112 (West)	(a) The department shall destroy any genetic material obtained from a child under this chapter not later than **the second anniversary** of the date the department receives the genetic material unless a parent, managing conservator, or guardian of the child consents to disclosure under Section 33.017(c-1). (b) The department shall destroy any genetic material obtained from a child under this chapter not later than the second anniversary of the date the department receives the genetic material if: (1) a parent, managing conservator, or guardian of the child consents to disclosure under Section 33.017(c-1); (2) the parent, managing conservator, or guardian who consented to the disclosure revokes the consent under Section 33.017(i); and (3) the department receives the written revocation of consent under Section 33.017(i) not later than the second anniversary of the date the department received the genetic material.
UT	Utah Admin. Code r. R398-1	The Department retains blood spots for a **minimum of 90 days**.
WA	Wash. Admin. Code 246-650-050	Retention/destruction: The specimen/information form shall be retained **until the child is twenty-one years old** in accordance with the requirements for hospitals specified in RCW 70.41.190. After this time the form will be destroyed.

Transfer of specimens:

State	Citation	Statute or Regulation Text
NE	181 Neb. Admin. Code Ch. 2, 2-007	l. A Material Transfer Agreement (MTA) between the **newborn screening** laboratory responsible for the storage and release of specimens and the specimen recipients. The MTA must address prohibitions on secondary transfer and secondary research of DBS without state authorization; data sharing back to the state program; intellectual property rights, publication requirements, and acknowledgement of state resource use in publications. 2. For every specimen released for research, with or without patient identifying information, the laboratory must document: a. Who had access to the specimen; b. To whom the specimen was released; c. The amount of specimen released; and d. Evidence from the research entity that written consents were obtained from the legally responsible parent or guardian of the individuals whose specimens were released. 3. The blood spot is not released for public health research until after the 90-day storage time. During the 90-day storage time, it must be available for clinical purposes for the patient. 4. Records required at 181 NAC 2-007.08A, items 1 and 2, must be retained for 25 years.

Two states are considering legislation relevant to research on dried bloodspots:

State	Bill Number	Summary	Status
CA	SB 170	This bill would authorize a parent or guardian of a minor child and the newborn child, once he or she is legally an adult, to request that the department destroy, not use for research purposes, or both, the blood sample, and the department would be required to do so. The bill would also require the department to prepare and provide informational materials, to be distributed as specified, regarding the newborn child blood sample collected pursuant to the program that includes, but is not limited to, information on storage, retention, and use of the blood sample, and the right of specified persons to request that the blood sample be destroyed, not used for research purposes, or both.	Referred to Coms. on P. & C.P. and HEALTH. - 02/02/2015
ND	SB 2334	The bill amends the ND statute as it relates to research on blood spots as follows: 25-17-07. Institutional review board. A person that conducts research on blood spots, other specimens, or registry data that is maintained by the department shall follow institutional review board processes for human research which must include obtaining parent or guardian authorization.	Introduced, first reading, referred Human Services Committee - 02/20/2015