



Wisconsin Newborn Screening Data and/or Dried Blood Spot Request Preview

Complete the following form to request data and/or dried blood spots from the Wisconsin Newborn Screening program.

The Wisconsin Newborn Screening program can typically accommodate single, moderate-sized data requests without assessing fees, but unusually large, complex and/or recurrent queries may incur costs requiring support from the data requestor.

Type of request

- What data are you requesting from the Wisconsin Newborn Screening Program?
(*select all that apply*)
 - ☐ De-identified data
 - ☐ Identifiable data (i.e., includes protected health information (PHI))
 - ☐ Dried blood spots

Requestor credentials

- Principal investigator's name
- Principal investigator's title
- Principal investigator's credentials (*select all that apply*)
 - ☐ MD
 - ☐ DO
 - ☐ PhD
 - ☐ APP
 - ☐ Lab Personnel
 - ☐ Genetic Counselor
 - ☐ Other: _____
- Principal investigator's institution name
- Principal investigator's phone number
- Principal investigator's email address
- Does the principal investigator have status to conduct human subjects research at their institution?
 - ☐ Yes
 - ☐ No
 - ☐ Unsure

- Is the principal investigator based in Wisconsin? *If the principal investigator is not based in Wisconsin, you need a co-investigator based in Wisconsin.*
 - ☐ Yes
 - ☐ No

Wisconsin co-investigator's credentials *(only required if principal investigator is not based in Wisconsin)*

- Wisconsin co-investigator's name
- Wisconsin co-investigator's title
- Wisconsin co-investigator's credentials *(select all that apply)*
 - ☐ MD
 - ☐ DO
 - ☐ PhD
 - ☐ APP
 - ☐ Lab Personnel
 - ☐ Genetic Counselor
 - ☐ Other: _____
- Wisconsin co-investigator's institution name
- Wisconsin co-investigator's phone number
- Wisconsin co-investigator's email address
- Does the Wisconsin co-investigator have status to conduct human subjects research at their institution?
 - ☐ Yes
 - ☐ No
 - ☐ Unsure

Data viewers

Provide the following information for all people (other than yourself) who will view the data provided.

Name	Title	Name of Institution	Email Address

Project description

- Provide a brief description of the proposed project. Justify the need for data and/or dried blood spots. (3-5 sentences)
- Provide a lay description of the proposed project. If the project is approved, this description will be posted on the DHS Newborn Screening website.
- Provide a brief summary of the importance of the proposed research. Please include how this research will improve child health and well-being, as this is an approval requirement.
- Is this research project funded? If so, please provide more information about the funding source.
- Please upload your full research protocol for use of data and/or dried blood spots.
- **If data is requested**
 - ☐ Describe the type/nature of the data you are requesting.
 - ☐ Upload a document outlining the data variables you are requesting.
- **If identifiable data is requested**
 - ☐ Explain why this project requires identifiable data.
 - ☐ How would you like the data securely sent and how will you securely store the data throughout this project?
- What is the proposed use of this data and/or dried blood spots? (*select all that apply*)
 - ☐ Internal use only
 - ☐ Quality assurance/quality improvement/public health demonstration project fitting US federal regulation definition
 - ☐ Abstract/poster/oral presentation
 - List all proposed conferences/venues.
 - ☐ Publication
 - ☐ Research

Wisconsin Department of Health Services and Wisconsin State Lab of Hygiene: Sharing Residual Dried Blood Spot for Research

Attestation (*only required if requesting dried blood spots*)

Dried blood spots (DBS) refer to Newborn Screening Program's residual dried blood spots.

Dried blood spots are stewarded by the Department of Health Services (DHS) and the WI State Laboratory of Hygiene (WSLH) Newborn Screening (NBS) Laboratory (Lab) for

the use of the Wisconsin Newborn Screening Program (NBSP) as defined by State statute.

Use of DBS for research is permissible under specific requirements and limitations, with the necessary approval from the WI NBSP.

Once an investigator has obtained both IRB and WI NBSP approval for use of DBS for research, the following protocol dictates transfer and usage:

1. Investigator works with the WSLH NBS Lab Director to obtain residual DBS as per the approved protocol.
2. No DBS will be released prior to 30 days after all routine NBS tests are completed.
3. All release of DBS is at the discretion of the WI NBS Lab. The Lab will release a portion of the DBS for approved research if the Lab Director is able to confirm clinical testing is completed and residual sample remains.
4. The Lab will release DBS in 3.2 mm punches. The released number of punches are based on the need and availability. Justification for releasing only a partial DBS sample is due to the potential future request for DBS for other clinical or research purposes.
5. The Lab will keep the remaining DBS during the defined research/project period, but not exceeding 5 years, so the investigator can request additional DBS sample as needed for the same approved research/project. The DBS will be destroyed at 5 years with no exceptions. DBS with NBS positive results are only available for research if they are not needed for quality assurance/quality improvement purposes in the Lab.
6. DBS will not be transferred to investigators for long-term storage or banking. Duration of investigator retention of the DBS for research must be specified in the investigator's protocol/consent form.
7. Sharing a portion of the deidentified DBS samples with outside investigators for research purposes is permissible under specific requirements. Material transfer agreements (MTAs) must include specific language so no attempts will be made to re-identify the samples. The investigator to whom the DBS are transferred agrees to destroy or return to the Lab any and all of the remaining DBS samples when the research is completed or after 5 years, whichever is earlier. They must notify the Lab in writing (email with confirmation of receipt suffices) once the sample is destroyed or returned.
8. Investigators must acknowledge they have used up all the DBS samples, or that they will destroy or return to the Lab all their remaining DBS samples, when the research is completed or after 5 years, whichever is sooner. They must notify the

NBSP in writing (email with confirmation of receipt suffices) once the sample is destroyed or returned.

- ☐ Name: _____
- ☐ Signature: _____
- ☐ Date: _____

Required documentation

- What is the status of the data transfer and use agreement with the Wisconsin Newborn Screening program?
 - ☐ In process
 - ☐ Executed
 - ☐ Not required
- What is the Institutional Review Board (IRB) status of this project?
 - ☐ IRB approved
 - Upload the IRB approval letter.
 - ☐ IRB under review
 - Include the estimated timeline for IRB approval.
 - ☐ IRB exempt/human subjects research
 - Upload the IRB exemption letter. If there is no IRB exemption letter, please upload documentation of discussion with the IRB or institutional official or other authority supporting exempt status. If you have no such documentation, explain why you believe the project is exempt.
- Was there or is there planned scientific review (i.e., National Institutes of Health grant application, American Heart Association, etc.)?
 - ☐ Yes
 - Please describe.
 - ☐ No

Additional information

- What is the deadline for this request to be fulfilled? The Newborn Screening Program needs a minimum of four weeks to fulfill requests.
- Have you discussed this project with a member of the Newborn Screening Program? All requests must have a Newborn Screening Program point of contact (Department of Health Services or Wisconsin State Lab of Hygiene staff). If you do not have a contact, one will be assigned.
 - ☐ Yes
 - Who is your Newborn Screening point of contact?
 - ☐ No

Acknowledgements

- I acknowledge the data and/or dried blood spots received may not be shared secondarily nor expanded beyond original proposed reported use without re-review by the Newborn Screening program.
 - ☐ I acknowledge
- **(If data is requested)** I acknowledge that I am required to meet with the Newborn Screening program collaborator and/or the Newborn Screening Data Reporting Specialist at least quarterly during the time period of the DUA.
 - ☐ I acknowledge
- I acknowledge that the Newborn Screening Program must review any publication utilizing this data and/or dried blood spots (i.e., presentation, publication, etc.).
 - ☐ I acknowledge
- I acknowledge that the Newborn Screening Program/staff must be listed in acknowledgements or co-authorship of any publications or presentations.
 - ☐ I acknowledge
- **(If data is requested)** I acknowledge that I must sign an Attestation of Destruction of Data at the end of the data use agreement period.
 - ☐ I acknowledge
- **(If dried blood spots are requested)** I acknowledge that I must destroy or return the dried blood spots to the lab after the earliest of five years or the research has ended.
 - ☐ I acknowledge

Questions

- Do you have any further questions?
 - ☐ Yes
 - List your questions below and a Newborn Screening staff member will be in touch.
 - ☐ No