



## **Iowa Newborn Screening Information System (INSIS) Confidentiality Policy**

INSIS is a statewide newborn screening information system managed by the Iowa Department of Public Health's Center for Congenital and Inherited Disorders. INSIS was developed to document timely newborn screening of all Iowa babies. Iowa's newborn screening programs include dried bloodspot screening through the Iowa Newborn Screening Program (INSP), hearing screening through the Early Hearing Detection and Intervention program (EHDI), and screening for critical congenital heart disease (CCHD).

### **Purpose of confidentiality policy**

The purpose of this policy is to address the need to provide appropriate confidentiality protection to the information in INSIS. The confidentiality of this information must be distinguished from issues of privacy. Privacy is concerned with the control individuals exert over the release of their personal information. Under INSIS's policy, confidentiality is concerned with how the information provided to INSIS by individuals is accessed, collected, stored, used, and provided to other individuals and organizations.

### **Definitions**

All terms used in this policy have the same meaning as those terms used in the state law and administrative rules that authorize INSIS.

1. "Authorized User" means a user of the INSIS who has completed an enrollment form that specifies the conditions under which the INSIS can be accessed and who has been issued an identification code and password by the Iowa Department of Public Health.
2. "Confidentiality" means:
  - a. Limiting the collection, access, use, storage, and release of information from enrolled users to INSIS and from INSIS to enrolled users in a manner that information will not be shared with non-enrolled users, and
  - b. Information will only be used for the purposes permitted under the applicable laws, rules, and policies.
3. "Newborn Screening Record" means information related to a newborn who receives or who refuses newborn screening in Iowa.

### **Confidentiality**

Based on the law (Iowa Code § 22.7(2) and 641IAC Chapters 3 and 4), rules, and general principles of confidentiality, the confidentiality policy for INSIS is as follows:

1. Newborn screening information, including identifying and demographic data maintained in INSIS, is confidential and may not be disclosed except in the following circumstances:
  - a. To the parent or legal guardian of the newborn screened, upon receipt of a signed release of information form.
  - b. Authorized users of INSIS who have completed an enrollment form that specifies the conditions under which the INSIS can be accessed and who have been issued an identification code and password by the department.
  - c. Persons or entities requesting newborn screening data in an aggregate form that does not identify an individual either directly or indirectly in compliance with the [IDPH Policy on Disclosure of Confidential Public Health Information, Records or Data](#).
  - d. Agencies that complete an agreement with the department which specifies conditions for access to INSIS data and how that data will be used. Agencies shall not use information obtained from INSIS to market services to patients or non-patients, to assist in bill collection services, or to

locate or identify patients or non-patients for any purposes other than those expressly provided in Iowa Administrative Code 641IAC4.

- e. A representative of a state or federal agency, or entity bound by that state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency is subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. State or federal agencies shall not use information obtained from the INSIS to market services to patients or non-patients, to assist in bill collection services, or to locate or identify patients or non-patients for any purposes other than those expressly provided in this rule.

### 3. Code of Fair Information Practices

The principles in the Code of Fair Information Practices will be applied to INSIS. This means:

- a. The existence of INSIS and its purposes will be made known to all patients, including parents or guardians as applicable;
- b. Patients, including parents or guardians as applicable, will be informed about what information is maintained in INSIS and how that information is used;
- c. Patients, including parents or guardians as applicable, may review records in INSIS;
- d. INSIS will assure the reliability of the information it creates, maintains, uses, or disseminates and will take precautions to prevent the misuse of the information it creates, maintains, uses, or disseminates.

### 4. Authorized users

Only authorized users of INSIS may provide information to or receive information from INSIS.

Information from the newborn screening record may only be shared as follows:

- a. With other authorized users
  - b. The parent or guardian of an infant or child or the adult individual for whom the report is made.
  - c. A primary health care provider, birthing facility, or submitting laboratory.
  - d. A representative of a state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency will be subject to confidentiality regulations which are the same as or more stringent than those in the state of Iowa.
  - e. A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.
5. Information from the newborn screening record may only be used by authorized users to contact parents of minor children for the purposes of informing the primary care provider, early intervention service providers, audiologists or ENT providers, or the newborn's parent or guardian to recommend follow-up care and resources for the newborn. This information may be accessible for entry and updates via the INSIS user interface for health care providers and their staff to ensure accurate data captures. However, use of this information is restricted to the purposes outlined in this policy.
  6. No information from INSIS will be made available to any party who is not an authorized user except as provided in item 4.
  7. All authorized users are required to complete an Individual User Agreement and to read and abide by this confidentiality policy.
  8. All authorized users may receive information from INSIS unless otherwise specified in the agreement between the authorized user and INSIS.
  9. No information from INSIS may be provided to any other party except as required by law.
  10. The INSIS database will maintain an audit trail for all information received from or released from INSIS.
  11. The Iowa Department of Public Health shall seek appropriate penalties for any misuse of information in INSIS by any authorized user or any other party, including federal civil penalties as defined in HIPAA rules (Federal Register/Vol. 68, No. 74/Thursday April 17, 2003/Rules and Regulations).
  12. Any paper copy of information from INSIS will be shredded before disposal.

**Requests for information**

Requests for information from INSIS will be handled in accordance with Policy #002 of the Center for Congenital and Inherited Disorders –Release of Data Policy and Procedure.

**Data retention and disposal**

INSIS is in compliance with the State Records Commission as all data is entered and maintained in electronic form for the life of the INSIS. Monthly, the full INSIS database is backed up and archived to tape. Monthly archive backups are maintained for one year.

**Voluntary Opt-Out**

In any circumstance where a parent or guardian specifically requests that information on their child be removed from INSIS or an adult over the age of 18 requests their information be removed, the record will be sealed. Such requests must be in writing, and should be sent to the attention of the Executive Officer of the Center for Congenital and Inherited Disorders.

Executive Officer  
Center for Congenital and Inherited Disorders  
Iowa Department of Public Health  
321 East 12th Street  
Des Moines, IA 50319-0075

**Prohibited Transfer of Data or Secondary Use of INSIS data**

Authorized users are not permitted to transfer data, either in paper or electronic form, to non-authorized users. Non-authorized users include, but are not limited to, software vendors, contractors, and quality improvement organizations. Potential users should be considered non-enrolled unless specifically approved in writing by the Iowa Department of Public Health in advance of data transfer.

**Research using INSIS data**

The Iowa Department of Public Health must approve requests for information from INSIS for research. Requests for INSIS data for research can made to the Executive Officer of the Center for Congenital and Inherited Disorders.

Executive Officer  
Center for Congenital and Inherited Disorders  
Iowa Department of Public Health  
321 East 12th Street  
Des Moines, IA 50319-0075

**Penalties**

The Iowa Department of Public Health shall seek appropriate penalties for any misuse of information in INSIS by any enrolled user or any other party, including federal civil penalties under HIPAA rules (Federal Register/Vol. 68, No. 74/Thursday April 17, 2003/Rules and Regulations) and enforcement under state law as appropriate.

**Review of confidentiality policy**

This policy shall be reviewed and revised as needed, but not less than annually.

### **Authorized Individual User Agreement**

The goal of universal newborn screening of all newborns in Iowa is early detection of congenital or inherited conditions to allow children and their families the earliest possible opportunity to obtain appropriate early intervention services. The Iowa Newborn Screening Information System (INSIS) is a statewide data system for dried blood spot screening, hearing screening, and critical congenital heart disease screening reporting of results and follow-up case management. The purpose of the system is to facilitate the transfer of data to the Iowa Department of Public Health to enhance the capacity of agencies and practitioners to provide services to children and their families in a timely manner. Authorized users have the ability to search for and update patient records and to assess the need for additional screening or referral.

In order to participate in the INSIS, this Individual User must agree to the following:

1. Only access information in INSIS for individuals under their care.
2. Read and abide by the INSIS Confidentiality Policy.
3. Use INSIS consistent with the INSIS Confidentiality Policy and Iowa law (Iowa Code § 22.7(2) and 641IAC Chapters 3 and 4).
4. Abide by all INSIS security policies and procedures, including safeguarding user name(s) and password(s) against unauthorized use.
5. Agree not to impose a charge or fee to the patient for use of INSIS or for any information obtained from INSIS.
6. Access records by only using the user's personal user name and password.
7. Agree not to mine the system for potential customers.
8. Agree not to release any screening or assessment data, except which is allowed by state law/rules.

**Failure to abide by this agreement may result in immediate termination, suspension or revocation of access to INSIS.**

This form must be signed by the user requesting access.

**By clicking "I accept" below, I sign and I agree to the above conditions and will abide in accordance with Iowa law.**