641—4.6(136A) Iowa registry for congenital and inherited disorders (IRCID). This program provides active statewide surveillance for congenital and inherited conditions and disorders. These may include birth defects, neuromuscular disorders, metabolic disorders, and all stillbirths. The program also may conduct active statewide surveillance of live births without a reportable congenital or inherited condition or disorder to serve as controls for epidemiological surveys. Surveillance activities for specific congenital and inherited conditions and disorders and maternal and congenital infections will be conducted for the period of time that adequate financial support is available.

A reportable congenital or inherited condition or disorder occurring in a miscarriage or pregnancy may be included in the IRCID.

4.6(1) *Surveillance policy.*

a. Congenital conditions and disorders, including birth defects, occurring in Iowa are reportable conditions, and records will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Congenital conditions and disorders surveillance will be performed in order to determine the occurrence and trends of such conditions and disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for congenital conditions and disorders, to contribute to prevention strategies, and to assist in the planning for and provision of services to children with congenital conditions and disorders and their families.

b. Records for neuromuscular disorders will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Neuromuscular disorders surveillance for individuals of all ages shall be performed to determine the occurrence and trends of the selected neuromuscular disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys through annual long-term follow-up, and to assist in the planning for and provision of services to individuals with selected neuromuscular disorders and their families.

c. Stillbirths occurring in Iowa are reportable conditions, and records of these stillbirths will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Stillbirth surveillance will be performed to determine the occurrence and trends of stillbirths, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for stillbirths, and to assist in the planning for and provision of services to prevent stillbirths.

4.6(2) *IRCID activities.*

a. The department will establish an agreement with the University of Iowa to implement the activities of the IRCID.

b. The IRCID will use the birth defects, neuromuscular disorders, and stillbirth coding schemes developed by the Centers for Disease Control and Prevention (CDC).

c. The IRCID staff will review hospital records, clinical charts, physician's records, vital records, prenatal records, and fetal death evaluation protocols pursuant to rule 641—1.3(139A), information from the INSP, RGCS, NMP, and the IMPSP, and any other information that the IRCID deems necessary and appropriate for congenital and inherited conditions and disorders surveillance.

4.6(3) *Department responsibility.*

a. When a live infant's medical records are ascertained by the IRCID, the department or its designee will inform the parent or legal guardian by letter that this information has been collected and provide the parent or guardian with information about services for which the child and family may be eligible.

b. The department and the IRCID will annually release aggregate medical and epidemiological information to medical personnel and appropriate state and local agencies for the planning and monitoring of services for children with congenital or inherited conditions and disorders and their families.

4.6(4) *Confidentiality and disclosure of information.* Reports, records, and other information collected by or provided to the IRCID relating to a person known to have or suspected of having a congenital or inherited condition or disorder are confidential records pursuant to Iowa Code sections 22.7 and 136A.7.

a. Personnel of the IRCID and the department shall maintain the confidentiality of all information and records used in the review and analysis of congenital or inherited conditions and disorders, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. IRCID staff are authorized pursuant to rule 641—1.3(139A) to gather all information relevant to the review and analysis of congenital or inherited conditions and disorders. IRCID staff are permitted to review hospital records, clinical charts, physician's records, vital records, and prenatal records, information from the INSP, RGCS, NMP, and IMPSP and any other information the IRCID deems necessary and appropriate for live births without a reportable congenital or inherited condition and disorder to serve as controls for epidemiological surveys.

c. No individual or organization providing information to the IRCID in accordance with this rule shall be deemed or held liable for divulging confidential information.

4.6(5) *Access to information in the IRCID.* The IRCID and the department shall not release confidential information except to the following, under the following conditions:

a. The parent or guardian of an infant or child for whom the report is made and who can demonstrate that the parent or guardian has received the notification letter.

b. An Early ACCESS service coordinator or an agency under contract with the department to administer the children with special health care needs program, upon receipt of written consent from the parent or guardian of the infant or child.

c. A local health care provider, upon receipt of written consent from the parent or guardian of the infant or child.

d. A representative of a federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The information provided shall not include the personal identifiers of an infant or child with a reportable congenital or inherited condition or disorder.

e. Researchers. All proposals for research using the IRCID data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher's institutional review board. Proposals shall then be reviewed and approved by the department before research can commence.

f. A representative of a state agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state agency will be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa.

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