641—4.7 (136A) Iowa registry for congenital and inherited disorders (IRCID). This program provides active statewide surveillance for congenital and inherited disorders. These disorders 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 disorder to serve as controls for epidemiological surveys. Surveillance activities for specific congenital and inherited disorders will be conducted for the period of time that adequate financial support is available.

4.7(1) *Definitions.*

a. Birth defects shall be defined as any major structural abnormality or metabolic disorder that may adversely affect a child's health and development. The abnormality or disorder must be diagnosed or its signs and symptoms must be recognized within the first two years of life.

b. Neuromuscular disorders shall be defined as Duchenne, Becker, congenital, distal, Emery-Dreifuss, fascioscapulohumeral, limb-girdle, myotonic, and oculopharyngeal muscular dystrophies.

c. Rescinded IAB 4/3/13, effective 5/8/13.

d. Stillbirths shall be defined as an unintended fetal death occurring after a gestational period of 20 completed weeks or an unintended fetal death of a fetus with a weight of 350 or more grams. Stillbirth is synonymous with fetal death.

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

4.7(2) *Surveillance policy.*

a. Congenital disorders, including birth defects, occurring in Iowa are reportable conditions, and records of these disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in the IRCID. Congenital disorders surveillance shall be performed in order to determine the occurrence and trends of such 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 disorders, to contribute to prevention strategies, and to assist in the planning for and provision of services to children with congenital disorders and their families.

b. Records for neuromuscular disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in the IRCID. Neuromuscular disorders surveillance for individuals of all ages shall be performed in order 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. Rescinded IAB 4/3/13, effective 5/8/13.

d. Stillbirths occurring in Iowa are reportable conditions, and records of these stillbirths shall be abstracted pursuant to 641—1.3(139A) and maintained in the IRCID. Stillbirth surveillance shall be performed in order 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.

4.7(3) *IRCID activities.*

a. The center shall establish an agreement with the University of Iowa to implement the activities of the IRCID.

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

c. The IRCID staff shall review hospital records, clinical charts, physician's records, vital records, prenatal records, and fetal death evaluation protocols pursuant to 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 disorders surveillance.

4.7(4) *Department responsibility.*

a. When a live infant's medical records are ascertained by the IRCID, the department or its designee shall 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 center and the IRCID shall 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 disorders and their families.

4.7(5) *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 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 disorders, including information which is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. IRCID staff are authorized pursuant to 641—1.3(139A) to gather all information relevant to the review and analysis of congenital or inherited disorders. This information may include, but is not limited to, hospital records, physician's records, clinical charts, vital records, prenatal records, fetal death evaluation protocols, information from the INSP, RGCS, NMP, and the IMPSP, and any other information that the IRCID deems necessary and appropriate for congenital and inherited disorders surveillance. 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 that the IRCID deems necessary and appropriate for live births without a reportable congenital or inherited 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.

4.7(6) *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 disorder.

e. Researchers, in accordance with the following:

(1) 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 and the IRCID's internal advisory committee before research can commence.

(2) The IRCID shall submit to the IRCID's internal advisory committee for approval a protocol describing any research conducted by the IRCID in which the IRCID deems it necessary to contact case subjects and controls.

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.

[**ARC 7981B**, IAB 7/29/09, effective 9/2/09; **ARC 0664C**, IAB 4/3/13, effective 5/8/13]