Ohio Administrative Code

Rule 3701-57-04 Confidentiality, research.

Effective: December 13, 2015

(A) Any information, data or reports with respect to a birth defects case that is furnished to, or obtained by, the birth defects information system or by the director shall be confidential and shall be used for one or more of the following purposes:

(1) For medical research studies including demographic, epidemiologic, teratologic, or similar studies related to health and health care provision;

(2) To inform parents, guardians and custodians of children with birth defects of medical care and other services available for the child and family;

(3) To provide data regarding birth defects in Ohio to the "National Birth Defects Prevention Network"; and

(4) To distribute reports of information as required by section 3705.36 of the Revised Code.

(B) Qualified persons or government entities engaged in demographic, teratologic, epidemiologic or similar studies related to health and health care provision may be given access to confidential information if all the following conditions are met and if the project is approved by the Ohio department of health's institutional review board:

(1) The person requesting to access the data initially meets with the birth defects program administrator or other pertinent Ohio department of health staff to discuss the proposed study concept and programmatic data elements requested.

(2) Following the outcome of paragraph (B)(1) of this rule, the person conducting the study submits a complete application to the Ohio department of health's institutional review board and provides written information about:

(a) The purpose of the study;

(b) The nature of the data to be collected;

(c) How the researcher intends to analyze it;

(d) The records the researcher seeks to review, and;

(e) The safeguards the researcher will take to protect the identity of the patients whose records the researcher will be reviewing.

(C) Based on the results from the meeting and written information submitted to the Ohio department of health's institutional review board under paragraph (B) of this rule, the director shall determine that access to confidential information concerning individuals with birth defects shall be made available to persons engaged in demographic, epidemiologic, teratologic, or similar studies related to health and health care provision if the person or government entity signs an agreement to maintain the confidentiality of the information and the study meets the following standards:

(1) The study had clearly defined goals that pertain to birth defects diagnosis, prevention, treatment or service coordination;

(2) For case control studies, the research design used in the study will involve a sufficiently large sample size that any meaningful difference between cases and controls will be statistically significant. For other projects, the study will provide enough cases for meaningful analysis of the data for identification of potential risk factors and intervention strategies for birth defects treatment and prevention; and

(3) The study will be conducted by researchers who have the ability to analyze and interpret data.

(D) The director may disclose information assembled by the birth defects information system with the written consent of the parent or legal guardian of the child who is the subject of the information.

(E) The director may obtain and merge into the birth defects information system information reported to the Ohio department of health under another provision of the Revised Code or Administrative Code.

(F) Notwithstanding paragraphs (A) and (C) of this rule, the Ohio department of health may release confidential information concerning individuals with birth defects or congenital anomalies to the birth defects information system of another state, if the other state has entered into a written reciprocal agreement with the Ohio department of health and the agreement provides that the state will comply with the confidentiality provision of this rule and that information identifying a child will not be released to any person without the written consent of the individual's parent or legal guardian.

(G) This rule does not prevent the release of information assembled by the birth defects information system in summary, statistical or other form that does not identify particular individuals or individual sources of information.