**Section 500.70 Availability of Medical and Health Information**

a) All reports issued by the Department that are aggregated to make it impossible to identify any patient or reporting facility, including the annual report, shall be made available to the public pursuant to the Access to Records of the Department of Public Health (2 Ill. Adm. Code 1127) and the Freedom of Information Act [5 ILCS 140].

b) All requests by bonafide researchers approved by the State Registrar seeking confidential vital records data and/or certificates must be submitted in writing to the Division of Vital Records. The request must include a study protocol that contains: objectives of the research; rationale for the research, including scientific literature justifying the current proposal; overall study methods, including copies of forms, questionnaires, and consent forms used to contact facilities, physicians, or study subjects; methods for the processing of data; storage and security measures taken to insure confidentiality of the registrant and parental identifying information; time frame of the study; a description of the funding source of the study (e.g., federal contract); and the curriculum vitae of the principal investigator and a list of collaborators. In addition, the research request must specify what identifying information is needed and how the information will be used.

c) All requests to conduct research and all modifications to approved research proposals involving the use of data and/or vital records certificates that include identifying information shall be subject to a review to determine compliance with the following conditions:

1) the request for identifying information contains stated goals or objectives;

2) the request documents the feasibility of the study design in achieving the stated goals and objectives;

3) the request documents the need for the requested data to achieve the stated goals and objectives;

4) the requested data can be provided within the time frame set forth in the request;

5) the request documents that the researcher has qualifications relevant to the type of research being conducted;

6) the research will not duplicate other research already underway using the same data; and

7) other conditions relevant to the need for the identifying information and the applicant's and parental confidentiality rights because the Department will only release identifying information that is necessary for the research.

d) Research Agreements

1) The Department will enter into research contracts for all approved research requests. These contracts shall specify exactly what information is being released and how it can be used in accordance with the standards in subsection (c). In addition, the researcher shall include an assurance that:

A) use of data is restricted to the specifications of the protocol;

B) any and all data and/or vital records certificates that may lead to the identity of any registrant or parent, research subject, physician, informant, other person, or hospital is strictly privileged and confidential, and the researcher agrees to keep all this data strictly confidential at all times;

C) all officers, agents and employees will keep all this data strictly confidential, will communicate the requirements of this Section to all officers, agents, and employees, will discipline all persons who may violate the requirements of this Section, and will notify the Department in writing within 48 hours of any violation of this Section, including full details of the violation and corrective actions to be taken;

D) all data provided by the Department pursuant to this contract may only be used for the purposes named in this contract and that any other or additional use of the data may result in immediate termination of this contract by the Department;

E) all data provided by the Department pursuant to this contract is the sole property of the Department and may not be copied or reproduced in any form or manner, and the researcher agrees to return all data and all copies and reproduction of the data to the Department upon termination of this contract or make assurances that data and/or vital records certificates will be properly shredded or incinerated;

F) any breach of any of the provisions of the research contract will void the contract. All data previously provided by the Department, including any copies of the data, regardless of form, will be returned to the Department immediately. No further data will be released to, nor research contracts entered into with, the principal investigator and collaborators for a period of time to be determined by the State Registrar.

2) Any departures from the approved protocol must be submitted in writing and approved by the Director in accordance with subsection (c)(2) prior to initiation. No identifying information may be released by a researcher to a third party.

e) In accordance with Jane Doe II v. Lumpkin, prior to the release to private researchers of any copies of birth records or data from the birth records that contain personal identifiers, the State shall first obtain informed consent from the mother to whom the record relates. In requesting this informed consent, the mother shall be provided with a brief description of the research project. Personal identifiers include names, social security numbers, addresses, or any combination of items that may divulge the identity of an individual listed on a Certificate of Live Birth. For the purposes of this Part, private researchers shall include all those researchers who are not employed by the federal government and those researchers not employed by and/or not having a personal services contract to conduct the research utilizing the requested data with any State or local governmental body. Under a governmental personal services contract, the work product and all drafts of the contract shall remain the property of the State or local government. Personal services contractors shall be considered custodians of vital records within the meaning of the Vital Records Act for the term of the personal services contract.

f) Informed consent shall include the written signature of the mother approving her participation in the private research project. Only after the Department receives informed consent from the mother approving the release of her medical data to the private researcher, may the Department release this data.

g) The Department shall disclose individual patient or facility information to the reporting facility that originally supplied that information to the Department, upon written request of the facility.

h) The patient identifying information submitted to the Department by those entities required to submit information under the Act and this Part is to be used in the course of medical study under Part 21 of Article 8 of the Code of Civil Procedure [735 ILCS 5/Art. 8, Part 21]. Therefore, this information is privileged from disclosure by Part 21 of Article 8 of the Code of Civil Procedure.

i) The identity of any facility or any group of facts that tends to lead to the identity of any person submitted to the Division of Vital Records is confidential and shall not be open to public inspection or dissemination. This information shall not be available for disclosure, inspection, or copying under the Freedom of Information Act [5 ILCS 140] or the State Records Act [5 ILCS 160]. Information for specific research purposes may be released in accordance with procedures established by the Department in this Section.

j) Every hospital shall provide representatives of the Department with access to information from all medical, pathological, and other pertinent records and logs related to the preparation of vital records. The mode of access shall be by mutual agreement between the hospital and the Department.

k) Notwithstanding the provisions of this Section, *all information submitted to the Adoption Registry is confidential and gathered by the State solely for the purpose of facilitating the exchange of updated medical data and contact information between adopted and surrendered persons and other registered parties* and shall not be released under this Section*. Disclosure of identifying information in violation of* the Adoption *Act is a Class A misdemeanor* (Section 18.8 of the Adoption Act).

(Source: Amended at 46 Ill. Reg. 20036, effective November 30, 2022)