**Section 710.230 Criteria for Approval of Alzheimer's Disease Research Act Proposals**

a) All requests by researchers for confidential data must be submitted in writing to the Department. The request must include a study protocol that contains: objectives of the research; rationale for the research, including scientific literature justifying 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 ensure confidentiality of patient identifying information; timeframe of the study; a description of the funding source of the study (e.g., federal contract); the curriculum vitae of the principal investigator and a list of collaborators. (See 42 CFR 2.a4(a)-(j), 2a.6(a)-(b), and 2a.7-(b).)

b) All requests to conduct research and modifications to approved research involving the use of data that includes patient identifying information shall be subject to a standardized review. The Department will enter into contracts for research that require the release of patient identifying information when requests meet the following conditions:

1) The request for patient 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 timeframe 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.

7) Other conditions relevant to the need for the patient identifying information and the patient's confidentiality rights.

c) The researcher shall include an assurance that use of data is restricted to the specifications of the protocol. Any departures from the approved protocol must be submitted in writing and approved by the Director prior to initiation. No patient identifying information may be released by a researcher to a third party.

d) The Department, by signed and reciprocating agreement, may disclose individual patient information concerning residents of another state to the individual's state of residence only if the recipient of this information is legally required to hold the information in confidence and provides protection from disclosure of patient identifying information equivalent to the protection afforded by Illinois law.

e) The patient identifying information submitted to the Department by those entities required to submit information under the Act, Alzheimer's Disease Research Act, and this Part shall be privileged and confidential and 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]. The prohibitions stated in this Section shall not apply, however, to that information that is made available under Section 710.40(a) and (b).

f) The patient identifying information submitted to the Department by those entities required to submit information under the Act, Alzheimer's Disease Research Act, and this Part will be used in the course of medical study under Article VIII, Part 21 of the Code of Civil Procedure [735 ILCS 5/Art. VIII, Part 21]. Therefore, this information is privileged from disclosure by the Medical Studies Part of Article VIII of the Code of Civil Procedure.

(Source: Amended at 25 Ill. Reg. 11159, effective September 1, 2001)