

TITLE 89: SOCIAL SERVICES
CHAPTER III: DEPARTMENT OF CHILDREN AND FAMILY SERVICES
SUBCHAPTER f: GENERAL ADMINISTRATION

PART 432
RESEARCH INVOLVING CHILDREN AND FAMILIES

Section

- 432.1 Purpose
- 432.2 Definitions
- 432.3 Responsibilities of the Research Review Board
- 432.4 Membership of the Research Review Board
- 432.5 Criteria by Which Proposed Research Will be Evaluated
- 432.6 Voluntary Assent of Minors and Consent of Adults and Families
- 432.7 Use of Experimental Drugs
- 432.8 Retention of Records
- 432.9 Final Approval of Research Involving Children and Families

AUTHORITY: Implementing and authorized by "AN ACT creating the Department of Children and Family Services, codifying its powers and duties, and repealing certain Acts and Sections herein named" (Ill. Rev. Stat. 1987, ch. 23, pars. 5001 et seq.) and implementing the National Research Act of 1974 (Pub. L. 93-348, July 12, 1974, 88 Stat. 342 as amended).

SOURCE: Adopted and codified at 5 Ill. Reg. 5842, effective June 5, 1981; amended at 13 Ill. Reg. 16411, effective October 15, 1989.

Section 432.1 Purpose

These rules describe the position of the Department toward research that proposes to involve children for whom the Department has legal responsibility and their families or which proposes to involve current or former families and children who are or have received Department services, or the records of such individuals.

Section 432.2 Definitions

"Maximum allowable risk" means the greatest tolerable risk the Department will permit to the children and families it serves. This risk must not be greater overall than would be normally encountered in the daily lives or in routine medical or psychological care or examination of a comparable group of Illinois children for whom the Department is not legally responsible. Since abused, neglected, dependent and other children for whom the Department is legally responsible and their families may already be psychologically or physically disadvantaged compared to the general population of children and families, minimal risk requirements for these children and families will be more stringent than for the general population.

RESEARCH INVOLVING CHILDREN AND FAMILIES

October 15, 1989 – PT 89.22

"Research" or "research project considered by the Department" means a formal investigation which is designed to develop, confirm or contribute to practical or theoretical knowledge of benefit to children and families, and which is proposed by persons who are not Department staff. The systematic gathering of data which does not include identifying information on clients, for purposes of evaluating services or for review of legal compliance by appropriate governmental agencies, is not considered to be research.

"Research Review Board" means a committee appointed by the Director to review proposed research projects which would be conducted by persons who are not Department staff and which would involve children and families currently or formerly served by the Department directly or through contact or formal agreement, or records of such individuals.

Section 432.3 Responsibilities of the Research Review Board

- a) The Research Review Board will receive, review and analyze all proposed research which would involve children and families served by the Department, or records of such children and families, and research proposed by Department providers. The Research Review Board may seek the advice of medical, technical and program experts to assist the Board in determining the scientific significance of the proposed research and the potential effect on the subjects. Services provided to Department clients as part of a research project are not reimbursable unless such services are directly covered under the contract with the Department which is executed prior to the research.
- b) The Research Review Board will make a recommendation to the Director of the Department on each research project. The recommendation will describe in specific detail whether or not the research meets acceptable criteria as defined in these rules and in 89 Ill. Adm. Code 431, Confidentiality of Personal Information. The recommendation will include dissenting or provisional opinions, if applicable, from the Research Review Board members and consultants.

Section 432.4 Membership of the Research Review Board

The Director of the Department will appoint at least three persons to the Research Review Board to serve annual terms which may be renewed. At least one Department attorney and one social worker will be appointed. The social worker and any other members, other than the attorney, may be selected by the Director from Department staff or from other qualified individuals who are not Department staff. The Director may select a former client(s) as a member(s) of the Research Review Board.

Section 432.5 Criteria by Which Proposed Research Will be Evaluated

- a) Proposed research involving children and families currently or formerly served by the Department submitted to the office designated by the Director, shall meet the following criteria:

RESEARCH INVOLVING CHILDREN AND FAMILIES

October 15, 1989 – PT 89.22

- 1) offers minimal risk to children and families served by the Department;
 - 2) assures that the safest procedures are used consistent with sound research design and methodology;
 - 3) makes adequate provision to protect the privacy rights of children and families and to maintain confidentiality of records;
 - 4) maintains human dignity;
 - 5) shows promise of producing, confirming, or otherwise advancing knowledge of child or family emotional or physical conditions;
 - 6) assures that subjects will be selected in an equitable manner consistent with the goals of the research whenever appropriate;
 - 7) assures that adults, older children and infants have been considered in that order for participation in the proposed research wherever appropriate; and
 - 8) assures that, when feasible, the research will be used for diagnostic and treatment purposes to directly benefit participating subjects.
- b) The time and inconvenience requested of children and families participating in research and the extra workload that may be borne by Department staff must be justified by the expected benefits derived from the research, and the soundness of the research design.
- c) Selection of children and families who may participate in research will not be based solely on administrative convenience, availability of a population living in conditions of social or economic deprivation, or convenient access to the population.

Section 432.6 Voluntary Assent of Minors and Consent of Adults and Families

Adequate provisions will be made for the voluntary assent of minors who are capable of assent and for the consent of adults who will be directly involved in such research through interviewing, completing research forms, or other forms of direct participation. The consent of parent(s), guardian or legal custodian of minor children directly participating in the research is also required. The consent of individuals whose case record data will be aggregated and whose anonymity will be preserved is not required.

Section 432.7 Use of Experimental Drugs

The Department shall not permit the purely experimental use of drugs in research. No drug of an experimental nature may be given or administered in any form or manner for research purposes to any minor served by the Department. These rules do not prohibit the use of experimental drugs on

RESEARCH INVOLVING CHILDREN AND FAMILIES

October 15, 1989 – PT 89.22

an individual case basis as provided for in Part 327, Permanency Advocacy Services. Such individual case decisions as described in Part 327 do not fall under the responsibility of the Research Review Board unless the case(s) is part of a research project.

Section 432.8 Retention of Records

- a) All records pertaining to the human subject aspects of approved research projects, including but not limited to consent forms, data collection instruments, population/sampling lists, shall be retained by the researchers for a period of at least thirty-six (36) months following termination of the research.
- b) Project records of the researchers shall be available upon request for inspection by the Department's Office of Audits, Office of Investigations or any other Department staff designated by the Director.

(Source: Former Section 432.8 renumbered to 432.9, new Section 432.8 adopted at 13 Ill. Reg. 16411, effective October 15, 1989)

Section 432.9 Final Approval of Research Involving Children and Families

- a) The Director of the Department of Children and Family Services or his designee, will make all decisions, including approval, approval with stipulations, or disapproval for each proposed research project involving Department clients.
- b) The Director, or his designee, shall have the benefit of all opinions of the members of the Research Review Board and any consultant or citizen consulted by the Research Review Board.

(Source: Section 432.9 renumbered from Section 432.8 at 13 Ill. Reg. 16411, effective October 15, 1989)