

SUBCHAPTER f: GENERAL ADMINISTRATION
PROCEDURES 432 RESEARCH INVOLVING CHILDREN AND FAMILIES
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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	Final Approval of Research Involving Children and Families

== 432.1 Purpose

432.2 Definitions

"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 to benefit children and families, and which is proposed by non-Department staff. Data collection 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.

432.3 Responsibilities of the Research Review Board

- a) The Research Review Board appointed by the Director in accordance with Rule 432.4 has the responsibility of receiving, reviewing and analyzing all proposed research projects which involve children and families who are current or former clients of the Department or their records.
- b) The Division of Policy and Plans, Office of Program Development and Support will serve in a coordinating capacity for the Research Review Board. The Office of Program Development and Support will review, summarize, and collate the research information and forward it to the Research Review Board.

The Office of Program Development and Support shall:

- 1) Perform staffing functions for the Research Review Board.
- 2) Provide information as requested by the Research Review Board.
- 3) Follow through on the decisions made by the Research Review Board by submitting a letter to the Director of decisions/ramifications.
- 4) Develop and update periodically procedures implementing Part 432 and coordinate the activities of the Research Review Board.
- 5) Maintain a tracking/information system of all research being done involving DCFS children.
- 6) Monitor the compliance of the researcher with the provisions set forth by the Research Review Board.

The Research Review Board shall establish such matters as time and place of meetings, methods of inter-board communications, formats for presenting its recommendations to the Director, etc. The Office of Program Development and Support will staff the Research Review Board meetings.

- c) The Research Review Board shall make its recommendations to the Director on each research proposal it receives within a reasonable time period. Its recommendations shall be based on considerations which include, but are not limited to the following:
- 1) Adequate provisions are made to protect the privacy of children and their parents and to maintain the confidentiality of data, as set forth by legal staff recommendations.
 - 2) Adequate provisions are made to prevent the overuse of any one group of children based solely upon administrative convenience, availability of a population, economic disadvantage, or racial, sex, ethnic, religious or other types of discrimination.
 - 3) Adequate provisions are made for monitoring solicitation of assent and permission as provided for in Section P432.6, "Voluntary Assent of Minors and Consent of Adults and Families".
 - 4) Adequate provisions are made to assure that the Department has clearance over any published work which contains research results involving children for whom DCFS is responsible.

== 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

Informed consent of both the subjects of research over the age of 14 years who are capable of such assent and any adults who will be directly involved in such research through interviewing, completing research forms, or other forms of direct participation shall be obtained. The consent of the parents, legal guardians, custodians or legally authorized representatives of minor children under the age of 14 years directly participating in the research shall also be obtained. The basic elements of information necessary to such consent include:

- 1) An explanation of the purpose of the research and the procedures to be followed.
- 2) An explanation of any discomfort or risk that the subject will experience through participation.
- 3) A description of any benefits that the subject will derive through participation.

- 4) An offer to answer any questions concerning the procedures.
- 5) An instruction that the person is free to withdraw his/her consent and to terminate participation in the project without prejudice.

Form CFS 311, Consent for Participation in a Research Project, will serve as a guideline for obtaining the required consents of both the subjects participating in the research and the consent of the parent or guardian.

The Office of Program Development and Support will keep a copy on file of all consent forms for approved research projects.

The subjects of research shall be given a copy of the consent form.

432.7 Use of Experimental Drugs

The Research Review Board will refuse permission for research requests which involve the use of drugs. The researcher shall be notified and informed of the prohibition contained in the rule.

432.8 Final Approval

- a) The Research Review Board will ensure that the requesting party is notified of the Director's decision, including approval with stipulations, or disapproval.

Form CFS 310, Memorandum of Understanding, will be required from the researcher before any research begins involving children for whom the Department has legal responsibility or for whom the Department has initiated services.

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RESEARCH INVOLVING CHILDEN AND FAMILLIES
February 1, 1996 – P. T. 96.5

APPENDIX A
GUIDELINES FOR SUBMITTING RESEARCH PROPOSALS TO THE
INSTITUTIONAL REVIEW BOARD

All research involving children and families served by the Department of Children and Family Services must be approved by the Institutional Review Board of the Department of Children and Family Services. Research involving the staff, foster parents, grantees and contractors of the Department may also require review. It is also expected that all protocols will follow the federal regulations 45 CFR Part 46 and 21 CFR Parts 50 and 56, as described in "The Federal Policy for the Protection of Human Subjects".

Additionally, the federal regulations concerning the use of children and, when appropriate, other classes of vulnerable people may restrict the research that may be conducted with children and families receiving services from the Department of Children and Family Services.

Review and acceptance by the Institutional Review Board does not constitute consent for research participation, nor does it assure that consent for research participation will be granted for children for whom the Department has legal responsibility. Acceptance by the Review Board only indicates that the research was found to adequately protect the rights of human subjects as presented to the Review Board. Research investigators are responsible for obtaining consent to participate from all subjects who are 18 years of age and older and from parents who retain guardianship of any children to be involved in the research, this includes children who are under the temporary custody of the Department. For children for whom the Department of Children and Family Services has guardianship, consent must be obtained from the Department's Guardianship Administrator or authorized agent in accordance with DCFS **Rules and Procedures 327**.

Required Submissions

In order for a research proposal to be considered for review, one copy of the following must be submitted:

- 1) The form **CFS 320, Protocol Submission Form**, (see attached to these procedures);
- 2) One full-length protocol (detailed research plan and design);
- 3) A "Summary of Proposed Research" (5 pages maximum) with sections numbered as follows:
 - I. **Purpose or hypotheses of study.**
 - II. **Potential knowledge to be gained.** The particular relevance of this knowledge to children and families, if any, should be specified. Any

RESEARCH INVOLING CHILDEN AND FAMILLIES
February 1, 1996 – P. T. 96.5

potential benefit of this research to the administrators, supervisors, or other staff of the Department of Children and Family Services may also be specified in this section.

- III. Description of study methodology and design.** This description should include how subjects will be involved (through observation, completing questionnaires, use of records, etc.) and, if applicable, how cultural sensitivity issues will be addressed in interviewing and interactive data collection. Also to be included are a description of the intervention and treatment and an indication of whether experimental manipulation will be involved. Medical research should indicate any drugs and the dosage to be received by both the control and experimental groups, as well as the duration of treatment. Consent for the use of experimental drugs for individual children must follow Department policy contained in **Rules 327, Permanency Advocacy Services, Section 327.5(c)**. If this protocol is a follow-up submission or re-submission, a brief summary of any changes made to the original submission must be included.
- IV. Description of sample.** This includes the legal status of the children to be involved, recruitment procedures, and inclusion and exclusion criteria. If the majority of the children to be involved in the research are in the custody or guardianship of the Department, the reason for selecting this population for the research should be explained, particularly if the research hypotheses do not address questions specific to this population. If the ethnic and gender mix of the sample is not proportionate with the population represented by the sample, the disproportionate sampling should be justified. Also any difficulties presented by the sampling procedures in the generalizing of results should be addressed.
- V. Potential risks and benefits.** This section must include an assessment of the level of risk and the type of risk (physical, psychological, legal, etc.). Include both objective risks and risks which might be perceived by the subjects. Describe procedures through which any objective risk will be minimized, and how perceived risks will be clarified for the subjects. If appropriate, describe alternative research methods that could have been used to minimize risk, and state why they were rejected. The special conditions or protections to be provided to children for whom the Department is legally responsible and their families should be specified. If a control group is utilized, any potential risks to these subjects should be addressed as well.

Medical research should identify alternative medical procedures and services which might be of benefit to subjects, if any. If applicable, the

RESEARCH INVOLVING CHILDEN AND FAMILLIES
February 1, 1996 – P. T. 96.5

findings of similar research conducted on adults and animals and the implications of conducting the research with children and/or infants should be summarized.

- VI. Consents.** Procedures to obtain and document informed legal consent and, in research involving children, informed voluntary verbal or written assent. Exact details concerning the obtaining of consent must be provided, such as how parents will be contacted in cases in which parents must provide consent. If participation incentives are given to subjects either in cash or kind, the measures taken to ensure that their informed consent is not influenced should be specified.
- VII. Incentives.** Specify any incentives given to subjects in either cash or kind and the plan for payment if the subject withdraws from the study early.
- VIII. Confidentiality.** Describe the procedures planned to maintain confidentiality of records and data.

Length of Proposals

Proposals should be a maximum of five pages.

Required Appendices

All proposals must also include as appendices:

- a) the legal consent and voluntary assent forms to be used;
- b) Copies of any survey, questionnaire, and/or written testing instruments to be used;
- c) Approval letters received from other institutional review boards. Note that approval from other institutions should have been received before submission to the DCFS Institutional Review Board.

Federal Restrictions

Federal regulations include certain restrictions which apply specifically to wards of the State involved in research. These regulations include:

- 1) Wards of the State cannot be used as subjects in research involving greater than minimal risk in which there is no benefit either directly to the child or to the class of children who are wards. An exception to this rule may be made

RESEARCH INVOLING CHILDEN AND FAMILLIES
February 1, 1996 – P. T. 96.5

when the majority of the sample does not consist of wards, but the child's school, camp, hospital or other similar institution has been selected to participate in the research.

- 2) Wards of the State cannot be selected as the majority of subjects in a study solely on the basis of their convenience to the researcher, regardless of the cost entailed in obtaining subjects from another population.
- 3) An advocate who is not compensated by the research project must be appointed to wards involved in research entailing more than minimal risk, unless the research provides direct benefit to the child and the relation of the benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Time Frames for Review and Notification

All protocols will be reviewed within six to eight weeks after the adequate submission of information and supporting documents. The Institutional Review Board will then forward its recommendation to the Director of the Department of Children and Family Services. The researcher will then be notified by mail of the Director's decision. Prior to the initiation of research, the researcher will be required to sign **CFS 310, Memorandum of Understanding**, as required by **Procedures Section 432.8, Final Approval**. Questions regarding this process should be directed to the Department's Planning, Research, and Evaluation Specialist specified on the attached Submission Form. Requests for exceptions to any of the required submissions should be addressed to the Director of Research through the Department's Planning, Research, and Evaluation Specialist.