Institutional Review Board
Guidelines for Submission of Medical Research Proposals

I. BACKGROUND INFORMATION:

All research involving children and families receiving services from the Illinois Department of Children and Family Services (DCFS, also referred to as "the Department") must be approved by the Department's Institutional Review Board (IRB). Research involving staff, foster parents, grantees and contractors of the Department may also require IRB review. For complete guidelines, please refer to DCFS Rules and Procedures 432: *"Protection of the Human Subjects of Research".* It is also expected that all protocols will follow the federal regulations 45 CFR Parts 50 and 56, described in the *"Federal Policy for the Protection of Human Subjects,"* published in the June 18, 1991, *Federal Register*.

Federal regulations concerning the use of children and other classes of vulnerable people may restrict the research that can be conducted with children and families receiving services from the Department. Specifically,

1) Youth in care 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 youth in care. An exception to this rule may be made when the majority of the sample does not consist of youth in care, but the child's school, camp, hospital, or other similar institution has been selected to participate in the research.

2) Youth in care of the state cannot be selected as the majority of the 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 for youth in care whenever research involves 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.

Review and approval by the Department's IRB does not constitute consent for participation in research, nor does it assure that consent for research participation will be granted for children in state guardianship. Approval by the IRB indicates that the research was found to adequately protect the rights of human subjects as presented to the IRB. Investigators are responsible for obtaining consent to participate from all subjects who are 18 years of age; written assent from subjects 12 years of age and older; and consent from all parents who retain guardianship of any children to be involved in research. For children under the guardianship of the state, consent must be obtained from the guardianship administrator.

In order to conserve natural resources and provide for an expedient review, the IRB prefers to receive proposals via email or in electronic format submitted on disk or CD. If you cannot submit your proposal, with all of the required components electronically, then you must submit **ten (10)** paper copies.

The DCFS IRB recognizes that most medical-related studies have already gone through other institutional review boards and that we are requesting some of the same information. It is not our intention for principal investigators to recreate the same information over again, so we have developed a stream-lined, expedited process for these proposals. An IRB review can generally occur within 1 week of submission, provided that all of the required proposal components are included.

II. PROPOSAL REQUIREMENTS

A complete medical proposal includes:

1. **A completed IRB Proposal Submission Form;**
2. **Approval letters from all other institutional review boards which are involved with the study;**
3. **The full-length research protocol [*detailed proposal*], along with sample consent forms and all other appendices.**

III. SUBMITTING YOUR PROPOSAL

Direct your completed IRB proposal to DCFS using any of the following submission methods.

By Email (preferred method): **Brooke.Taylor@illinois.gov**

By Mail: ***Full proposal packet, including all instruments to be used, required!***

Brooke Taylor, IRB Coordinator
IL Dept. of Children & Family Services
DCFS
6201 South Emerald
Chicago, IL 606021

IV. THE IRB DECISION

Because it is often necessary for adjustments to be made to a proposal as a result of the IRB review, it is advisable to submit your proposal as soon as possible. After satisfactory review occurs, the IRB forwards its recommendation to the Director of the Department of Children and Family Services for a final decision. You will be notified of the decision as soon as possible and will be required to sign a Memorandum of Understanding if your study is approved. Failure to return the signed Memorandum of Understanding within 10 days of receipt automatically invalidates your approval; therefore, it is important that you watch for this document which will accompany your approval letter.

V. QUESTIONS OR ADDITIONAL INFORMATION

If you have any questions or need additional information regarding the review process, contact Brooke Taylor at (773) 371-6509 or by email at **Brooke.Taylor@illinois.gov**