Institutional Review Board
Guidelines for Submission of Non-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 CFRF 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 meets on a monthly basis, generally on the 4th Tuesday of each month. Non-medical proposals must be received no later than one week prior to the scheduled meeting in order to be placed on the meeting agenda.

II. PROPOSAL REQUIREMENTS

A complete non-medical proposal includes the following, to be submitted in the order in which they are listed:

1. **The completed IB Research Protocol Submission Form;**

2. **A 4-5 page Summary of the Proposed Research** - addressing, at a minimum, the following items in the order in which they are listed. The summary of your proposed research should address, at a minimum, the following sections in the order in which these are listed. If a particular section is not applicable to your study, a detailed explanation should be provided within the context of the proposal under the appropriate section.

   a. *Purpose or Hypotheses of the Study:* Provide a clear explanation of the hypotheses or purpose for conducting the study.

   b. *Potential Knowledge to be Gained:* The particular relevance of this knowledge to youth in care and custody-involved children and families, if any, should be specified. Any potential benefit of the research to administrators, supervisors, or other staff of the Department may also be outlined in this section.

   c. *Description of Study Methodology and Design:* Provide a description of the study that includes 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. Include a description of the intervention or treatment and indicate whether experimental manipulation will be involved. Medical research should indicate any drugs or dosage to be received by the control group and experimental groups, as well as the duration of treatment. If the protocol is a follow-up or a re-submission, please follow your description with a brief outline of any changes made to the protocol.

   d. *Description of Sample:* Description of the sample should include the legal status of children to be involved, recruitment procedures,a nd inclusion and exclusion criteria. If the majority of children to be involved in the research are in the custody of the guardianship of the state, 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, address any difficulties presented by the sampling procedures in the generalizing of results.

   e. *Potential Risks and Benefits:* Describe any potential risks and benefits to subjects, including assessment of level of risk and type of risk (physical, psychological, legal, etc.). Include both objective risks and risks that might be perceived by subjects. Describe procedures through which any objective risk will be minimized and how perceived risks will be clarified for subjects. If appropriate, describe alternative research methods that could have been used to minimize risk, and state why they were rejected. The specific conditions or protections to be provided to youth in care, custody-involved children and their family, as a particularly vulnerable class of subjects should be specified. If a control group is utilized, any potential risks to these subjects should be specified as well.

Medical research should identify alternative medical procedures and services that might be of benefit to subjects, if any. If applicable, the findings of similar research conducted on adults and animals and the implications of conducting the research with children and/or infants should be summarized.

f. *Incentives:* Describe any monetary or in-kind incentives which will be offered to participants.

The IRB's position on research incentives is that payment(s) ***cannot*** be "conditional" or pro-rated based on level of participation. When subjects sign a consent form to participate in research, they have a right not to answer any question they don't want to and to discontinue participation at any point during the process. We are absolutely diligent about about avoiding situations in which withholding/reducing an incentive payment could be construed as inducement to a person to give up their rights. Therefore, your proposal must contain a plan for payment if the subject withdraws from the study early.

g. *Confidentiality:* Describe the planned procedures to maintain confidentiality of records and data.

h. *Informed Consent/Assent:* Procedures to obtain and document informed consent and, in research involving children, informed written consent. Exact details concerning obtaining consent must be provide, such as how parents will be contacted in cases where parents must provide consent. (Refer to the Guidelines for Developing Consent to make sure you have included all of the necessary elements of consent.) If participation incentives are given to subjects either in cash or in-kind services, the measures taken to ensure that their informed consent is not influenced should be specified.

3. **The Informed Consent Checklist -** with the consent and/or assent forms attached; (Please note that approval from other institutional review boards should be received before submission to the DCFS IRB);

4. **The Full-Length Research Protocol** – including a full detailed description of the study along with all appendices (i.e., surveys, questionnaires, written interview/testing instruments, etc.)

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
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 well in advance of your planned initiation. Every effort is made to resolve concerns quickly but, in some cases, working through any problems that arise can take several weeks. After satisfactory review occurs, the IRB foryouth in care 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