Illinois Department of Children and Family Services
DCFS Office of Research and Development
Consent Procedures

This document provides researchers with guidelines to be used in the development of informed consent procedures and sample forms. There are certain elements that, according to Federal law (45 CFR Subtitle 46.116), must be included in obtaining consent of human research subjects. Following are some basic elements that should be included in informed consents. This is not all-inclusive, but should serve as a checklist for researchers to ensure that at a minimum, the following elements are included *(please note that we have included some definitions at the end of this document):*

BASIC ELEMENTS OF INFORMED CONSENT:

The following information shall be provided to each subject:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment (if any) that might be advantageous to the subject;
- A statement describing the event, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty of loss of benefits to which the subject is otherwise entitled;

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) currently unforeseeable;

- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

- Any additional costs to the subject that may result from participation in the research;

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

- The approximate number of subjects involved in the study.

COMMON MISTAKES & HELPFUL HINTS

In reviewing content procedures and forms, there has been a pattern of items typically omitted from proposed forms and procedures. Following are some of the more common omissions that researchers should be certain are included in proposed forms and procedures:

1. A conclusion is never enough. For instance, a form that simply states "I have read and agree to participate" is not enough. Similarly, one paragraph is never enough. Look over the federal law cited above, and ensure that all of the elements are include in the form.

2. An application or registration form does not constitute consent.

3. If minors are going to be interviewed, an assent form will be required for children 12 years and older.

4. Case file reviews: There are three state statutes that need to be complied with when researchers review DCFS case files: the Mental Health and Developmental Disabilities Confidentiality Act, the HIV Confidentiality Act, and the Foster Parents Confidentiality Act. These acts govern the review of case files, and one or all may be applicable to your research.

5. If the study involves the review of case records by researchers employed outside the Department of by the Department, the application should clearly state which portion of the case file needs to be reviewed (for example, the child abuse and neglect reports, psychological information, records of visitation…). This will help in determining which laws apply. Please note, however, that additional laws may be pertinent. For instance, if the researcher will be reviewing educational records, this may involve consent from the school in addition to DCFS.

6. Researchers must sign a statement that they will not re-disclose the confidential information gathered during the study period.

7. The language used in consent forms should be simple. This includes consent forms for minors, foster parents, and biological parents. It should not contain professional jargon. A participant should not be made to feel coerced into participating in a study; rather participation should be voluntary. As provided by federal law, the form should also clearly state that participation in the study will in no way effect provision of DCFS services, or benefits.

8. Consent forms should be translated into Spanish. If the consenter does not speak English or Spanish as her or his primary language, and there is no form available in their native language, the form should be translated orally and then a separate form must be signed by the translator and the consenter saying that he or she has orally translated the document and that the subject understands and agrees to participate. Please contact DCFS if you need a copy of the form to be used for this purpose.

9. For employees of the Department, special care should be taken to ensure that there is no confusion between the employee's role as a Department employee and as a researcher. Department staff should state explicitly how they plan to avoid this confusion in their proposal.

WHO GRANTS CONSENT?

The Department's Guardianship Administrator provides consent for children who are under the guardianship of DCFS. Participation of all other children, including those under temporary custody, requires the consent of their parents and/or legal guardians.

DEFINITIONS:

Assent - Agreement by an individual not competent to give legally valid informed consent (e.g., an older child or an incompetent person) to participate in research.

Maximum Allowable Risk - 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.