# INFORMED CONSENT CHECKLIST

This checklist is intended to provide researchers submitting proposals to the Illinois Department of Children and Family Services with guidelines to be used in the development of informed consent procedures and forms. According to Federal Law (45 CFR Subtitle 46.116), certain elements must be included to obtain the consent of human subjects. The list below is not all-inclusive, but shall serve as a Checklist for researchers to ensure that “at a minimum” the following elements are included.

Please attach this Checklist to consent forms (if applicable) and submit with the proposed research study.

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
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<tbody>
<tr>
<td>Research Title:</td>
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</tbody>
</table>

## TYPE OF CONSENT:

- #1 = Foster Parent/DCFS Staff Consent;  
- #2 = Biological Parent/Legal Guardian Consent  
- #3 = Child Assent

For each consent form, please indicate Yes, No, or Not Applicable (N/A)

<table>
<thead>
<tr>
<th>YES/NO</th>
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<th>YES/NO</th>
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<tbody>
<tr>
<td>N/A</td>
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</tbody>
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The research study indicated above involves:

- a) Human Subjects, (check this box [ ] if subjects include minors)
- b) Confidential Client Records (*check this box [ ] if mental health records included)
- c) No more than “Minimal Risk”
- d) Greater than Minimal Risk

The consent form(s) attached include the following basic elements of consent:

1) A statement that the study involves research

2) An explanation of the purpose of the research

3) The expected duration of subject’s participation

4) A description of the procedures to be followed

5) Identification of any procedures which are experimental

6) A description of:
   - a) any benefits to the subjects;
   - b) any reasonably foreseeable risks or discomfort to the subjects

7) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

8) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

9) An explanation of whom to contact for answers about:
   - a) the research study
   - b) the subject’s rights as a research subject
   - c) a research-related injury

10) A statement that:
    - a) participation is voluntary;
    - b) “refusal to participate” will involve no penalty or loss of benefits to which the subject is otherwise entitled; and
    - c) the subject may “discontinue participation” at any time without penalty of loss of benefits to which the subject is otherwise entitled.

11) For research involving “more than minimal risk,” provide an explanation of:
    - a) whether or not any compensation will be given; and
    - b) whether or not any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained.

**NOTE:** If you have answered “NO” to any of the elements of consent stated in items 1 – 11, please attach an explanation.

*If mental health records are needed, please complete the attached form CFS 600-3 or the elements contained therein may be incorporated within your existing consent form(s). Refer to the Mental Health and Development Disabilities Confidentiality Act for details. Researchers must also be aware of the HIV confidentiality Act, Foster Parents Confidentiality Act and any other federal or state statutes related to Substance Abuse Client Confidentiality.*
In addition to the basic elements of consent indicated above, when appropriate, researchers must also include one or more of the elements of consent listed below:

<table>
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<td>FOR EACH CONSENT FORM</td>
</tr>
<tr>
<td>PLEASE INDICATE YES, NO, OR NOT APPLICABLE (N/A)</td>
</tr>
<tr>
<td>12) A statement that a particular treatment or procedure may involve risks to the subjects (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable</td>
</tr>
<tr>
<td>13) Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent</td>
</tr>
<tr>
<td>14) Any additional costs to the subject that may result from participation in the research</td>
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<tr>
<td>15) The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject</td>
</tr>
<tr>
<td>16) 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</td>
</tr>
<tr>
<td>17) The approximate number of subjects involved in the study.</td>
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</tbody>
</table>

PLEASE ATTACH THIS COMPLETED CHECKLIST TO YOUR CONSENT FORM(S).