# APPLICATION FOR CHILD ABUSE RESEARCH

State Form 116 (R4 / 11-24)

Name of Project

*Applications should be sent directly to:*
*Research and Evaluation Director,*
*Department of Child Services*
*302 W. Washington St., Room E306*
*Indianapolis, IN 46204*

## GENERAL INFORMATION

The Indiana (IN) Department of Child Services (DCS) is concerned with the protection of the rights and welfare of human subjects in all research, development and related activities. DCS is concerned with protection of right to privacy, the need for informed consent, protection of confidentiality of data and records and protection against physical, psychological, social and legal risks. The uses of graphic, written or recorded information, while presenting no physical risks to the subjects, may create medicolegal risks or expose the subject to public embarrassment or humiliation through breach of confidentiality and invasion of privacy.

The major focus of a project may not be the sole determinant of the risks involved or the need for protection. The safeguarding and confidentiality of medical records, case reports, minutes and other forms of data collected on individuals and groups and the use of such data either by the investigator / teacher / director conducting the research, concurrent use of the data by other investigators or use of the data for research purposes at a later time are considered within the scope of concern of this policy.

If the proposal involves human subjects, records, or both, the applicant shall:

(1) Describe the nature and purpose of the research proposal with particular attention to the characteristics of the proposed subject population and explain the rationale for using this subject population whose ability to give voluntarily informed consent may be in question;

(2) Describe and assess any potential risks (e.g. physical, psychological, social, legal or other) and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used;

(3) Describe consent procedures to be followed, including how and by whom documentation of informed consent will be obtained,

(4) Describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks and an assessment of their effectiveness;

(5) Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work; and

(6) Evaluate the risk - benefit ratio.

When physical or psychological risks to human subjects are involved, state the extent to which the researcher / teacher / director will be responsible for their medical care and how potential subjects will be selected from a population available. These statements are subject to review, approval and modification or disapproval by the Director of DCS or their designee.

## DEFINITIONS

Definitions applicable to the following section:

“At risk” means any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development or related activity which departs from the application of those established and accepted methods necessary to meet the individual's needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

“Informed consent” means the knowing consent of an individual or the individual's legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or any other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed and their purpose, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

An instruction that the person is free to withdraw consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

“Researcher” shall include a bona fide professional, or a bona fide student at an accredited college or university who is practicing or majoring in certain academic areas which have an interest in child welfare. Examples include but are not limited to the fields of sociology, psychology, law, criminology, health education, medicine and child development.

***WRITE ALL PROPOSALS USING THE FOLLOWING FORMAT AND HEADINGS:***

(A) Purpose and Nature - Briefly describe the purpose and nature of the research proposal, state the benefit, if any, that is to be gained by the subject(s) or what information is to be added to the general body of knowledge as a result of this research.

(B) Procedures - List all human subjects or procedures to be used with a description of those considered beyond already established and accepted techniques.

(C) Safeguards - Describe the necessary safeguards to be used to protect the subject(s) and / or case record(s) including maintaining the confidentiality of records.

(D) Level of Risk - State whether or not you consider the subject to be " *at risk* ". * If you consider the subject to be " *at risk* ", in what respect do the potential benefits to the subject or contributions to the general body of knowledge outweigh the risks.

(E) Protection - If you consider the subject to be " *at risk* ", state precisely what you tell the subject in lay language to obtain informed consent per definition ** relative to each procedure wherein the subject is " *at risk* ". This must be a form that is given or read to the subject particularly for this purpose. Please attach copy of form.

(F) Documentation of Informed Consent - State how you will obtain documentation of " informed consent ". ** Answer even if subject is not considered "*at risk* ". *Do not use "inapplicable ".*

* Subject at risk means any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development or related activity which departs from the application of those established and accepted methods necessary to meet the individual's needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

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(1) A fair explanation of the procedures to be followed and their purpose, including identification of any procedures which are experimental;
(2) A description of any attendant discomforts and risks reasonably to be expected;
(3) A description of any benefits reasonably to be expected;
(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
(5) An offer to answer any inquires concerning the procedures; and
(6) An instruction that the person is free to withdraw consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

*As the signatures at the bottom of this form attest, the researcher(s), principal investigator(s), teacher(s), and director(s) are pledged to conform to the below precepts and conditions:*

As one engaged in investigation utilizing human subjects and / or case records, I acknowledge the rights and welfare of the child, client, patient or human subject involved. I acknowledge my responsibility as an investigator to secure the informed consent of the subject by explaining the procedures, in so far as possible and by describing the risks as weighed against the potential benefits of the investigation.

I am in agreement with the above-stated research principles; and I understand that in research, a fundamental distinction must be recognized between research in which the aim is essentially therapeutic for a patient, and research in which the essential object is purely scientific and without therapeutic value to the person subjected to the research.

I understand that the information requested is confidential and agree to comply with state and federal statutes concerning confidentiality. I also understand that I cannot contact the families and children involved with the Department of Child Service unless expressly authorized by the Department of Child Services.

I agree to release, indemnify and hold harmless the Director of the Department of Child Services, that person's agents, employees, contractors or assigns from any and all claims and liability from litigation resulting from or alleged to have resulted from the Researcher's acquisition of documents and /or information held by the Department of Child Services. This indemnification shall apply to any alleged act or omission, whether negligent or whether committed by the Researcher or the Department of Child Services and shall include all court costs and reasonable attorney's fees.

If there is any reason whatsoever for me to deviate from these precepts, I will seek and obtain prior approval in writing from the Director, Department of Child Services.

| **SIGNATURE(S) OF ATTESTATION** | | |
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| Signature of Investigator(s) | Name(s) Typed | Date (*month, day, year*) |
| Phone Number | Email | |
| Signature of Principal Investigator(s) | Name(s) Typed | Date (*month, day, year*) |
| Phone Number | Email | |
| Signature of Teacher(s) | Name(s) Typed | Date (*month, day, year*) |
| Signature of Program Director(s) | Name(s) Typed | Date (*month, day, year*) |
| *The Application for Child Abuse Research has been reviewed and approved I disapproved by the Director or the Director's designee.* | | |
| Signature of Director or the Director's Designee | | Date (*month, day, year*) |