



THE FLORIDA CENTER
FOR CHILD AND FAMILY DEVELOPMENT

PROCEDURE

Title/Subject: Research Protocol and Protections			
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Approved By:		Title: Chief Executive Officer	
Approved By:		Title: Program Vice President/CQI Chairperson	
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Any research The Florida Center for Child and Family Development (The Florida Center) participates in or permits will be conducted in accordance with all applicable legal requirements.

When research opportunities are identified that could provide a benefit to the persons that we serve, or subsequent persons served, The Florida Center will convene an internal review board (IRB) to analyze the ethical principles and regulatory requirements of participation. In order to approve a research project involving human subjects, the IRB must assure that:

- ✓ The prospective subject population is appropriate in terms of characteristics and number.
- ✓ The recruitment of subjects will be free of coercion.
- ✓ The experimental design is sound.
- ✓ Any risks associated with the research project are minimized to the greatest extent possible.
- ✓ The potential benefits are maximized to the greatest extent possible.
- ✓ The risks to the subject are outweighed or balanced by the potential benefits.
- ✓ The level of subject remuneration (if any) is fair and non-coercive.
- ✓ The degree to which confidentiality is maintained is acceptable.
- ✓ The method used to obtain informed consent is ethically and legally acceptable.
- ✓ The principal investigator has the appropriate qualifications, experience and facilities to conduct the research.

Upon completing the review of the proposed research, the IRB will report to the Chief Executive Officer and the Board of Directors, and:

- ✓ Provide information and make recommendations regarding the ethics of the research.
- ✓ Make a recommendation as to whether or not to approve the research proposal.

The IRB will be responsible for monitoring all ongoing research activities. The frequency of monitoring activities and specific monitoring protocols will be designed to address each research activity The Florida Center conducts.

Participation in any research will be voluntary. The Florida Center staff will never threaten to withdraw services or coerce persons served into participating in any research activity. The use of financial incentives to potential research participants in the recruiting process is prohibited.

A consent form will be developed by the principal investigator for each research activity entered into, and will address the specific information relating to the research protocol. Each research participant, or his/her parent or legal guardian, will sign a consent form that includes:

- ✓ A statement that participation is voluntary and refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled. The statement will include a description of any consequences, if any, that may arise due to a decision to withdraw.
- ✓ A statement that The Florida Center will continue to provide services whether or not he/she agrees to participate.
- ✓ A statement that the project is research and an explanation of the nature and purpose of the research, including the expected duration of the subject's participation.
- ✓ A statement of any anticipated benefits the subject or others might reasonably expect. If there is no direct benefit to the subject, this will be stated.
- ✓ A clear description of the possible risks or discomfort. If the risk potential is currently unknown or un-measurable, a statement to that effect will be required.
- ✓ A statement that any new information developed during the course of the research that might affect the subject's willingness to continue participation will be provided.
- ✓ A statement describing the method by which confidentiality of records identifying the subject will be maintained, who is entitled to access to those records, how long they will be kept, and the final disposition.
- ✓ The participant's signature.
- ✓ The signature of a witness to the signature.

All information given to the subject or his/her legally authorized representative, will be in simple, easily understood language. If the subject is not English-speaking, informed consent will be presented in whatever language is appropriate. If a potential subject is illiterate, the investigator will use a competent witness to verify voluntary informed consent. A signed copy of the consent will be provided to the subject or his/her legally authorized representative. Copies of all informed consents will be retained for a minimum of three (3) years after completion of the research. The principal investigator is responsible for the maintenance and retention of such records.

The identity and privacy of persons served in all phases of a research project will be safeguarded. Statistical analyses, case examples, reports and summaries will be compiled and presented in a manner that masks the identity of the subjects. All subjects will be identified for these purposes with unique identifiers as specified in the research protocols developed for the particular research design.

Should The Florida Center participate in any research that is governed by a state or independent IRB process, the agency will comply with all standards of that protocol.