CF OPERATING PROCEDURE
NO. 215-8

STATE OF FLORIDA
DEPARTMENT OF
CHILDREN AND FAMILIES
TALLAHASSEE, March 24, 2017

Safety

INSTITUTIONAL OVERSIGHT OF HUMAN SUBJECT RESEARCH AND INSTITUTIONAL REVIEW BOARD DESIGNATION

1. Purpose. The intent of this operating procedure is to provide a structured framework within which Department staff and contracted providers proposing or conducting research can ensure that the rights of the individuals that the Department serves, and its employees, are protected. It is the policy of the Department of Children and Families to uphold its assurance as filed with the federal Department of Health and Human Services' (HHS) Office for Human Research Protections (OHRP).

2. Scope. This operating procedure is applicable to all Department and contracted provider staff who engage in, plan to engage in, or are asked to authorize or support research using human subjects within the Department's areas of responsibility.

3. References.

a. 45 Code of Federal Regulations (CFR), Subparts 46, 160, 162, and 164.

b. 21 CFR, Subparts 50, 56, 312 and 812.

c. Health Insurance Portability and Accountability Act of 1996 (HIPAA).

d. Terms of Assurance, Office of Human Research Protections, Department of Health and Human Services (https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html).

e. The Belmont Report, 1979 (https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html).

4. Definitions. For the purposes of this operating procedure, the following definitions shall apply:

a. Agents. Agents of the Department include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

b. Assent. The affirmative agreement to participate in research. Assent is required even if the individual's parent (of child) or legally authorized representative (for child or adult) provides consent. Failure to voice objection to participate in research does not qualify as assent. Children under 7-years-old do not have the cognitive ability to assent.

c. Assurance. An agreement that establishes standards for human subject research as approved by the Office for Human Research Protections.

d. Belmont Report. A report that was issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to explain the fundamental ethical principles that should guide the conduct of research involving human subjects.

e. Child. As per s. 39.01(12), Florida Statutes (F.S.), a child or youth means an unmarried person under the age of 18-years-old who has not been emancipated by order of the court.

f. Department. Department of Children and Families.

g. Dissent. An individual's negative expressions, verbal and/or non-verbal, that he/she objects to participation in the research or research activities.

h. Human Subject.

(1) An individual about whom an investigator (whether professional or student) is conducting research obtains:

(a) Data (of any kind) through intervention or interaction with the individual; or,

(b) Private identifiable information (see definition below) even in the absence of intervention or interaction with the individual.

(2) For purposes of this operating procedure, human subjects also include any Department employees, or persons being served by the Department or by one or more of its contracted providers, whose relevance to the research is based on his or her connection with the Department or who is otherwise within the Department's areas of responsibility and authority.

i. Intervention. Physical procedures by which data are gathered and/or manipulations of the subject or the subject's environment that are performed for research purposes.

j. Interaction. Communication or interpersonal contact between the investigator(s) and the research participant, or review of their private identifiable information.

k. Institutional Review Board (IRB). A review body established or designated by an organization to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research. To be used by a project covered in this operating procedure, an IRB must be in good standing with the Office for Human Research Protections of the U.S. Department of Health and Human Services.

l. Legally Authorized Representative. An individual authorized under applicable law to grant permission for services, treatment, benefits or other activities as determined by the court on behalf of another person.

m. Memorandum of Understanding. A formal written agreement between the Department of Children and Families and another institution.

n. Private Identifiable Information. This includes any information that may be linked to the identity of the subject as defined by HIPAA (e.g., Social Security Number, birth date, agency case number, address, health plan number, or other demographic information). For the purposes of human subject research, it also includes information about any behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place.

o. Provider. Any service provider that contracts with the Department to provide services to populations of individuals or families on behalf of the Department. A contracted provider is an agent of the Department for the purposes of this operating procedure.

p. Research. A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

5. General.

a. Institutional Commitments.

(1) The Department shall safeguard the rights and welfare of human subjects in research by ensuring that all human subject research receives approval through a federally approved Institutional Review Board(s), consistent with general policy established in section 381.86, F.S., and 45 CFR 46, 160, 162 and 164.

(2) The Department shall safeguard the rights and welfare of human subjects in clinical research (of Food and Drug Administration regulated products, including drugs, devices, or biologics) through rule set forth by the U.S. Food and Drug Administration's Human Subject Regulations (21 CFR 50, 56, 312, 812) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

(3) The Department shall uphold the ethical principles of the *Belmont Report* found at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html and apply Health and Human Services regulations (45 CFR 46, including subparts A, B, C and D) to all proposed research which is funded or supported by the Department of Health and Human Services or any other federal funding source. The ethical principles set forth in the *Belmont Report* are summarized as follows:

(a) Respect for Individuals. Recognition of the personal dignity and autonomy of individuals and the special protection of those persons with diminished autonomy or vulnerability.

(b) Beneficence. The term is often understood to cover acts of kindness or charity that go beyond strict obligation. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.

(c) Justice. Persons are treated with fairness in the distribution of research benefits and burdens. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., recipients of financial assistance, racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands that these not provide advantages only to those who can afford them, and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

(4) The Department shall offer training free of charge for Department employees and provider staff who engage in research. The OHRP Training Modules are available at https://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp. Training is also available through the Collaborative Institutional Training Initiative (CITI) on-line course hosted by the University of Miami at https://www.citiprogram.org/.

b. Human Subject Research/Non-Research Determinations.

(1) The Department's Human Protections Administrator has the authority to determine whether activity represents "human subject research" or not in accordance with federal regulation.

(2) Investigators do not have the authority to make an independent determination of what activity qualifies as not being human subject research. Investigators shall submit a request in writing to the Department's Human Protections Administrator to make this determination. Requests can be sent to: Human Protections Administrator, Department of Children and Families, Office of Child Welfare, 1317 Winewood Blvd., Building 1, Tallahassee, FL 32399.

c. Enrollment of Vulnerable Populations in Research (specifically, children, pregnant women, individuals with mental illness or mental retardation, or prisoners).

(1) Consistent with federal regulations in 45 CFR 46 and 21 CFR 50 and 56, all research involving vulnerable populations as listed above require special assurances. The Institutional Review Board is required to ensure that these special assurances are met.

(2) Children will be enrolled in research only with the signed consent of parents or a legally authorized representative, such as a guardian or the court. Where appropriate, there must also be an indication of the child's own assent to participate (when the child is capable of providing such assent). A waiver of assent can only be granted by the Institutional Review Board.

(3) At no time shall a child in the custody of the Department be allowed to participate in a clinical trial that is designed to develop new psychotropic medications or evaluate the suitability of providing medications previously approved for adults to children. This paragraph does not preclude research that evaluates the consequences of administration of psychotropic medications to children in state care.

(4) Adults who have a legally authorized representative will be enrolled in research only with signed consent from the legally authorized representative and assent from the individual. A waiver of assent can only be granted by the Institutional Review Board.

(5) It is the responsibility of any Department employee or provider agency aware of proposed research involving children or adults in any way to alert the appropriate Department program office and the Department's Human Protections Administrator as soon as it is known. The intent is to ensure that the investigator(s) is(are) aware of policy and Institutional Review Board requirements, and that research does not begin until approval is received from the Institutional Review Board and the Department's Human Protections Review Committee, as described below.

d. Florida Statewide Advocacy Council.

(1) The Florida Statewide Advocacy Council has access to Institutional Review Board meetings and to the Department's Human Protections Review Committee for all research proposed involving any adult or child served by the Department or its providers, per section 402.166(7)(d), Florida Statutes. If the Florida Statewide Advocacy Council has any concerns, the Council may express those concerns to the Human Protections Administrator or to the Institutional Review Board directly.

(2) The Human Protections Administrator will serve to resolve any issues that the Florida Statewide Advocacy Council may have with the proposal concerning constitutional or human rights.

6. Procedures.

a. Maintenance of a Federal-Wide Assurance (FWA).

(1) The Department's Federal-Wide Assurance #FWA00004629 shall be maintained by the Deputy Secretary, who is the signatory official for the Department and registered with the Office for Human Research Protections.

(2) The Deputy Secretary shall appoint a Department employee to function as the Human Protections Administrator. The primary role of the Human Protections Administrator is to ensure that Department employees, providers, and anyone acting as an agent of the Department comply with the Assurance and this operating procedure.

(3) The Human Protections Administrator shall renew the FWA every five years and ensure that any Memoranda of Understanding (or interagency agreement(s)), when warranted) are maintained.

(4) The Signatory Official and Human Protections Administrator shall complete the OHRP Training Modules (see https://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp).

b. Institutional Review Board (IRB) Designation.

(1) In lieu of its own IRB, the Department shall agree with and designate one or more Institutional Review Boards outside of the Department that have valid designations as active Institutional Review Boards with the Office of Human Research Protections. These IRBs shall be listed on the Department's Federal-Wide Assurance (FWA). Current agreements are listed in Appendix A to this operating procedure.

(2) The Department requires that any person or entity that wants to conduct research involving individuals who are receiving services from~~,~~ or on behalf of~~,~~ the Department, or involves Department employees, has written approval from an IRB and must provide a copy of the approval notification to the Department's Human Protections Administrator.

(3) In addition to IRB approval, the investigator must also have Department approval to conduct human subject research.

(4) A contracted provider is considered to be an agent of the Department, and, as such, is covered under the Department's Federal-Wide Assurance.

(5) When a contracted provider receives federal funding for research as a result of a grant from the Department of Health and Human Services (HHS) either through a contract with the Department of Children and Families, or directly from HHS, the investigator is required to seek approval from an IRB listed on the Department's FWA. However, if the provider has its own IRB or selects another IRB in good standing with the Office of Human Research Protections, the investigator may seek IRB approval through the provider's designated IRB. If this designated IRB is not listed on the Department's FWA, the investigator must work with the Human Subjects Administrator to ensure its addition to the FWA.

(6) When the research is unfunded or funded by any source other than the federal government, the investigator may use any IRB as long as the institution has a valid and active IRB designation by the OHRP.

(7) If the investigator is not an employee or agent of the Department, he/she shall complete an Individual Investigator Agreement (Appendix B to this operating procedure) prior to approval from the Department's Human Protections Review Committee (see paragraph 6c below).

(8) The investigator is responsible for any fees charged by an IRB. Research projects specifically requested or designed by the Department could result in fees. The Department will pay the fees through contract or agreement with the IRB, or through a payment mechanism with the investigator, such as a contract or Purchase Order.

(9) Investigators must comply with the principles established in the *Belmont Report*, this operating procedure, the policies and procedures of the Institutional Review Board, and all references herein.

(10) The Department shall execute a Memorandum of Understanding with each Institutional Review Board listed in its FWA.

c. Establishment of the Department's Human Protections Review Committee (HPRC).

(1) The HPRC shall be established by the Department's signatory official to review and approve all human subject research activity prior to the research beginning to ensure that the scope of the research falls within the mission of the Department. This committee is not an Institutional Review Board and does not replace the need for IRB approval; however, its permission to conduct the proposed research is required. This committee shall include appropriate program office personnel designated to serve on the committee by the Deputy Secretary of the Department.

(2) The HPRC shall be chaired and coordinated by the Human Protections Administrator. The HPRC shall meet as needed to review all research proposals submitted.

(3) The HPRC shall consider the following in its review of research proposals:

(a) Whether the research falls within the mission of the Department;

(b) Whether the research is duplicative of other research;

(c) Whether the research places an undue burden on Department resources; and,

(d) Whether the research meets the standards of quality research. Standards of quality research include reliability, validity, generalizability, and credibility.

(4) This internal review serves the purpose of alerting the appropriate program office of the proposed research and giving the appropriate personnel the opportunity to express support, withhold support, and discuss concerns. The concerns will be communicated to the investigator through the Human Protections Administrator as soon as possible following the meeting. The Department shall provide the investigator with a written statement of approval or disapproval within 5 days of the HPRC meeting, or following the resolution of any concerns.

(5) The Department reserves the right to disallow any research proposal, regardless of IRB approval. However, all research must receive HPRC and IRB approval prior to commencement. Program offices of the Department may require additional review and approval processes, but authorization is subject to final decision by the Human Protections Review Committee.

d. Submission of Research Proposals for Department Review.

(1) All research proposals, regardless of funding source and IRB approval, must be electronically submitted via email to the Department's Human Protections Administrator. The contact information for the Human Protections Administrator can be found on the Department's website at http://www.dcf.state.fl.us/admin/publications/humanResearch.shtml.

(2) Researchers shall submit the following for Department review:

(a) The Proposed Research Project Summary. (See Appendix C to this operating procedure.)

(b) A signed Individual Investigator Agreement.

(c) The IRB application packet.

(d) An IRB letter of approval.

(e) Any other relevant documentation related to the research project that is requested by the Department.

e. Reporting of Research Results. Researchers are required to submit a copy of the research results upon completion of the study to the Human Protections Administrator.

f. Reporting of Adverse Events. The Human Protections Administrator will ensure prompt reporting of the following events to the Department's Deputy Secretary, the HPRC, the IRB who approved the research project, and the Office of Human Research Protections:

(1) Unanticipated problems involving risks to subjects or others;

(2) Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB; and,

(3) Suspension or termination of HRPC or IRB approval.

BY DIRECTION OF THE SECRETARY:

(Signed original copy on file)

DAVID L. FAIRBANKS
Deputy Secretary

SUMMARY OF REVISED, DELETED, OR ADDED MATERIAL

The operating procedure has been updated to conform with current department policy on human subject research. Specifically, changes in the operating procedure include:

1. Web addresses have been updated.
2. A sentence has been added to the definition of "Assent" in paragraph 4b which states that children under 7 years old cannot give assent.
3. The time requirement for renewal of the Federal-Wide Assurance has been changed to reflect current law.
4. Appendices A and B have been updated, and Appendix C added.
5. Requirements for submission of research proposals for HPRC review have been established.
6. Factors that the HPRC considers in its review have been specified.

Institutional Review Boards Listed on Department of Children and Families' Federal-Wide Assurance

FWA # (if any)	IRB registration #	Institution Name
	1ORG0000689	IntegReview IRB

Individual Investigator Agreement

Name of Institution with the Federal-wide Assurance (FWA): Florida Department of Children and Families

Applicable FWA #: FWA00004629

Individual Investigator's Name:_____

Specify Research Covered by this Agreement:_____

Institutional Review Board:_____

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(1) The above-named Individual Investigator has reviewed: a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federal-Wide Assurance (FWA) for International (Non-U.S.) Institutions); b) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); c) the FWA and applicable Terms of the FWA for the institution referenced above; and d) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) listed above and will accept the final authority and decisions of the IRB/IEC, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB/IEC prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB/IEC any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB/IEC review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB/IEC any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB/IEC.

(9) The Investigator acknowledges and agrees to cooperate in the IRB/IEC's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB/IEC in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB/IEC.

(11) Emergency medical care may be delivered without IRB/IEC review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature:_____ Date_____

Name:_____ Degree(s):_____
(*Last*) (*First*) *(Middle Initial)*

Address:_____ Phone #:_____

_____
(*City*) (*State/Province*) (*Zip/Country*)

FWA Institutional Official (or Designee):_____ Date_____

Name:_____ Institutional Title:_____
(*Last*) (*First*) (*Middle Initial*)

Address: Department of Children and Families, 1317 Winewood Blvd. Phone #:_____

Tallahassee, FL. 32399, USA
(*City*) (*State/Province*) (*Zip/Country*)

Proposed Research Project Summary

1. **Date:**

2. **Project Title:**

3. **Principal Investigator:** [Include contact information]

4. **Affiliation(s) and/or Sponsor(s):** [Also, describe the status of any interaction with a Community-Based Care Lead Agency (CBC) or service provider, including the level of support, and whether the project was initiated by the Department or the CBC]

5. **Proposed Project Time Frame:** [When does the requestor want to start and end the project? Please note that research cannot begin until Department approval is granted.]

6. **Funding Source(s):** [If federal or state government, provide the specific source.]

7. **Other Key Project Participants and Contacts:** [Include contact information]

8. **Institutional Review Board:** [Include the name and FWA number of the Institutional Review Board that approved this research project.]

9. **Project's research question:**

10. **Population to be involved in project activity:** [Please describe the connection of the selected population to the Florida Department of Children and Families. Include location, age, characteristics that led to inclusion in project, etc. Is this statewide, or restricted to certain geographic areas?]

11. **Proposed interaction with subjects:** [Survey, focus group, interview, observation, intervention, etc. If project is data only, describe what is to be collected, including specific data elements sought, frequency, etc.]

12. **Is there any potential workload, including data extraction, for the Department or Community-Based Care Lead Agency or service provider staff? If yes, describe.**

13. **Does research require a Data Sharing Agreement or similar agreement?** If yes, please provide the completed and signed agreement or explain what needs to be done to secure the agreement.

14. **Please describe in detail the project's approach, methodology, and expected outcome or results.**

15. **If the project involves the use of specific interventions or control group(s), or otherwise includes any aspect where certain subjects in the project might experience different treatment or receive additional supports, please describe the rationale and necessity for the approach.** For example, is this an evaluation of a grant project that has been funded for a restricted set of participants but all participants will benefit from the grant? Or, is it an analysis of data about subjects who are in pre-existing situations, whether different or similar? Or, has the project chosen to randomly assign participants to treatments/control groups that might be perceived as "better" or "different" for the purposes of experimental design?

16. **What level and type of risk, either emotional or physical, is there to the subjects as a result of participating in this project? If there is risk, how will it be minimized?**

17. **Describe the intended use of the project.** For example, publication, dissertation, grant support?