State of Florida
Department of Children and Families

Ron DeSantis
Governor

Chad Poppell
Secretary

DATE: February 7, 2019

TO: Regional Managing Directors
Community-Based Care Lead Agency CEOs
Sheriff's Offices Conducting Child Protective Investigations

FROM: Patricia Babcock, Deputy Secretary

SUBJECT: CFOP 215-8 Institutional Oversight of Human Subject Research and Institutional Review Board Designation

PURPOSE: The child welfare operating procedure for human subject research (CFOP 215-8) has been updated. This memo highlights changes to CFOP 215-8 that will go into effect upon publication. The revised publication supersedes the operating procedure that was last published on March 6, 2017.

BACKGROUND: In May 2016, a new Department Human Protections Administrator was appointed, and a Human Protections Review Committee (HPRC) was formed in accordance with CFOP 215-8. The committee determined that CFOP 215-8 needed further revision to clarify the review process of proposed research projects.

Specifically, changes in the operating procedure include the following:

1. Web addresses have been updated.
2. The American Psychological Association has been added as a reference.
3. Definitions have been added and revised.
4. Appendices B (Individual Investigator Agreement) and C (Proposed Research Project Application) have been revised.
5. References to the Florida Statewide Advocacy Council have been removed.

ACTION REQUIRED: Please share this memorandum with appropriate child welfare staff and partners.

CONTACT INFORMATION: If you require additional information or have any questions, please contact Jodi Abramowitz, Human Protections Administrator, at 850-717-4470 or Jodi.Abramowitz@myflfamilies.com.

ATTACHMENTS
CFOP 215-8

cc: Chad Poppell, Secretary
David R. Mica Jr, Chief of Staff
John Jackson, General Counsel
Scott Stewart, Assistant Secretary for Administration
Rebecca Kapusta, Assistant Secretary for Operations
JoShonda Guerrier, Assistant Secretary for Child Welfare
Jennifer Lange, Assistant Secretary for Economic Self-Sufficiency
John Bryant, Assistant Secretary for Substance Abuse and Mental Health
Robert Anderson, Adult Protective Services Director
Patti Grogan, Refugee Services Director
Grainne O'Sullivan, Statewide Director, Children's Legal Services
Office of Child Welfare Directors
Regional Family and Community Services Directors
Center for Child Welfare

CF OPERATING PROCEDURE
NO. 215-8

STATE OF FLORIDA
DEPARTMENT OF
CHILDREN AND FAMILIES
TALLAHASSEE
February 7, 2019

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 for review of proposed research so that the Department can ensure that the rights and welfare of the individuals that the Department serves, and its employees, are protected. This structured framework for review includes that the physical, psychological, legal, and/or social risks to subjects are minimized and, when present, are justified by the importance of the research, and are agreed to by the subjects. 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 Department employees, contracted providers, and anyone acting as an agent of the Department 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).

f. American Psychological Association, 2017, Ethical Principles of Psychologists and Code of Conduct, Section 8; Research and Publication.

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. An affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as 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, 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. Credibility. The extent to which findings are believable and trustworthy.

g. Department. Department of Children and Families.

h. Human Subject.

(1) An individual about whom an investigator (whether professional or student) 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 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. Generalizability. The extent to which research findings and conclusions can be applied to the larger population from which the sample was selected. While the dependability of this extension is not absolute, it is statistically probable.

j. 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.

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

l. 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 have a valid and active IRB with the Office for Human Research Protections of the U.S. Department of Health and Human Services.

m. Legally Authorized Representative. An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research.

n. Memorandum of Understanding (also known as Memorandum of Agreement). A formal written agreement between the Department of Children and Families and another institution.

o. 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, 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, as well as any data

that could potentially identify a specific individual, distinguish one person from another, or could be used for de-anonymizing anonymous data.

p. 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.

q. Reliability. The extent to which measurement or results are consistent.

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

s. Validity. The extent to which results are accurate and measure what they purport to measure.

t. Vulnerable Populations. In the context of research, vulnerable populations include any individuals who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

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 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 rules 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 vulnerable populations.

(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 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://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training. 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 via email to HQW.OGC.HumanProtections.Administrator@myflfamilies.com.

c. Enrollment of Vulnerable Populations in Research.

(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, unless their parental rights have been terminated, or the court or a legally authorized representative. 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.

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, Human Protections Administrator, and Human Protections Review Committee members shall complete the OHRP Training Modules (see https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training).

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 through a grant from the Department of Health and Human Services (HHS) either through a grant or 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, that has a valid and active IRB 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 which should be negotiated as a part of any research agreement. The Department may 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 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 meets the ethical principles outlined in the *Belmont Report*;

(c) Whether the research properly assesses the risks and benefits outlined in the *Belmont Report*;

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

(e) Whether the research meets the standards of quality research including 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 by a member of the HPRC 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/general-information/human-subject-research/.

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

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

(b) A signed Individual Investigator Agreement. (See Appendix B to this operating procedure.)

(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:

Original with signature on File.

_____
PATRICIA BABCOCK
Deputy Secretary

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*)

Department of Children and Families
Human Protections Review Committee (HPRC)
Proposed Research Project Application

1. **Date of submission** (Please note that the Department HPRC meets monthly to review submissions. Research cannot begin until Department HPRC approval is granted.)**:**

2. **Research Project Title:** (should be the same as on the IRB application)

3. **Principal Investigator:** (should be the same name and contact information as IRB application)

    a. **Research Project Affiliation(s) and/or Sponsor(s):** [Please include whether the research was initiated and/or supported directly by the Department, a contracted Community-Based Care Lead Agency (CBC), or Managing Entity (ME). If so, please provide a letter of approval/support.]

    b. **Please describe any anticipated workload to the Department, CBC, or ME.** Please include data extraction, data collection, data reporting, etc. Please describe the expected role of the Department and/or a CBC or ME throughout your research.

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

    d. **Other Key Project Participants and Contacts:** [Include contact information and roles on the project]

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

    a. Is the IRB considered to be in good standing with the Office for Human Research Protections of the U.S. Department of Health and Human Services? (**click here for more information**: https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc)

    b. **IRB-Approved Project Time Frame:** [Please include the approved begin and end dates for the project. Please note that research cannot begin until Department HPRC approval is granted.]

5. **Research question:**

    a. **Population to be involved in research:** [Please include the connection of the selected population to the mission and/or the jurisdiction/purview of 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?]

    b. **Does the research involve human subjects as defined by the Department?**

        1. **Does the proposed research require data of any kind through an interaction or intervention with individuals?** Include location, age, characteristics that led to inclusion in project, etc. Is this statewide, or restricted to certain geographic areas?

2. **Does the proposed research require private identifiable information as defined below?** Include location, age, characteristics that led to inclusion in project, etc. Is this statewide, or restricted to certain geographic areas?

3. **Are individual subjects selected to provide this data or is the private identifiable information relevant to the research <u>based on his or her connection with the Department?</u>**

4. **Are individual subjects selected to provide this data or is the private identifiable information related to individuals <u>in the custody of or otherwise under the responsibility and authority of the Department?</u>**

<u>Private Identifiable Information</u>. 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.

c. **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.]

d. **If the research includes data collection only, is a Data Sharing Agreement (DSA) or similar agreement required, and if so, has a DSA been acquired?** If yes, please provide the completed and signed agreement or explain what needs to be done to secure the agreement.

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

   a. **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?)

   b. Please specify how you will identify and contact participants.

   c. Please define how the results of your research can be considered reliable, valid, credible and generalizable.

   d. 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?

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

7. **Please describe level of effort by the Principal Investigator to discover similar or identical research to your proposal.** Please include citations for this research. Please describe whether the proposed research duplicates or enhances existing research.