POLICY TITLE: Institutional Review Board		PAGE 1 OF 6
	CHILD AND FAMILY SERVICES AGENCY **Approved by: Raymond Davidson** Agency Director **Date: October 15, 2015**	**REVISION HISTORY:** October 16, 2002 May 15, 2007 September 14, 2010
LATEST REVISION: September 17, 2015	**EFFECTIVE DATE:** October 16, 2002	

I. AUTHORITY	The Director of the Child and Family Services Agency ("CFSA" or "Agency") adopts this policy to be consistent with the Agency's mission and applicable federal and District of Columbia laws and regulations, including the *LaShawn A. v. Bowser Implementation and Exit Plan* (December 17, 2010); D.C. Official Code Title 4, Chapter 13 and Title 16, Chapter 23; and 45 CFR 46 Subparts A, D and 34 CFR 97 Subpart A (U.S. Department of Health and Human Services Human Research regulations).
II. APPLICABILITY	This policy is applicable to the Institutional Review Board ("IRB") members, and researchers identified as "principal investigators" defined by the HHS Office of Human Research Protection as the scientist or scholar with primary responsibility for the design and conduct of a research project. Such research involves human subjects (referred to herein as "clients") by obtaining identifiable private information or data through intervention or interaction with the individual. "Research" is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.
III. RATIONALE	The purpose of having an IRB is to protect the rights, welfare, and privacy of research clients. To ensure that adequate protections are in place for any CFSA client participating in such research, CFSA established an IRB that is authorized to approve, require modifications, or disapprove research activities involving CFSA clients within its jurisdiction as specified by federal regulations. As such, CFSA's IRB is the cornerstone of protection for research involving any CFSA client.
IV. POLICY	It is CFSA's policy that the IRB membership reviews all human behavioral research protocols and proposals to ensure that the safety and privacy of participating CFSA clients are secured. CFSA does not approve research involving pharmaceutical or biomedical products or devices. This policy ensures an appropriate assent or informed consent process for CFSA clients involved in research. For the purpose of this policy, assent and informed consent have two distinct meanings relative to the age of the client.
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VI. PROCEDURES	**Procedure A: IRB Membership and Responsibilities** IRB membership consists of five members who carefully review and vet research proposals and activities to ascertain acceptability or potential conflicts relating to institutional policy and regulations, applicable federal and local laws, and standards of professional conduct and practice. IRB members ensure that risks to participating CFSA clients are minimal or non-existent. All reviews are conducted by CFSA's IRB. Additional details concerning IRB processes are outlined in the IRB business process. For purposes of this policy, the term "client" includes infants, children, youth up until age 21, parents, guardians and custodians who are receiving or have received services from CFSA; the policy is also applicable to other research participants such as caregivers and employees. 1. On occasion, IRB membership may need to select and include additional individuals with special expertise in subject matters, pertaining but not limited to the following groups: a. Children diagnosed with medical or mental health conditions b. Children living under severe economic or educational disadvantage c. Pregnant or parenting youth d. Children or youth who self-identify as lesbian, gay, bisexual, or transgender e. Youth who are or have been involved with the juvenile justice system 2. IRB membership responsibilities include but are not limited to fulfilling the following obligations: a. Convene a minimum quorum of four IRB members for decision-making b. Conduct quarterly meetings for review of proposals c. Prepare and maintain adequate documentation of IRB activities and minutes of meetings d. Balance a determination of participating client's rights with societal benefits of scientific research, including modification of research activities as necessary to protect the interests of CFSA clients e. Ensure fair selection of CFSA clients for research participation f. Conduct continual reviews of research participants to ensure protective measures are in place (e.g., no risks to a CFSA client's physiological, psychological, or social characteristics) g. Observe and monitor research activities or selection of a third party to do the same, including collection and analysis of data as appropriate

	h. Present research projects to the director of CFSA i. Conduct at least one annual review of research projects and determine which projects require review more than annually 3. Any IRB member aware of a conflict of interest or any circumstance that could result in an undue influence that may constitute a conflict of interest must immediately inform the IRB chairperson. • No IRB member should participate in any review where there is a conflicting interest, other than providing information as requested by the chairperson.
	Procedure B: IRB Review of Proposals 1. Individuals interested in doing research that includes CFSA clients must complete a CFSA *IRB Proposal Application* and submit it for review by the IRB. 2. Approval must not be given to any research that does not include the signed, legally-effective informed consent of a client 18 years of age and older, or for clients younger than 18 years of age who have not attained the legal age for consent to participation, assent of the child and permission of the child's parents or guardian. 3. Reviews of a low or no-risk research proposal may be expedited after a determination is made by a quorum of four IRB members. 4. The expedited review procedure must not be used for classified research involving clients. 5. Tabling of a proposal review may occur if additional or clarifying information is needed to move forward with a determination. 6. After review of a proposal, IRB membership has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to clients. 7. Once approved, research activities cannot be changed without an IRB review. 8. Before any changes are made to research activities approved by the IRB, the primary investigator must submit to the IRB an outline of proposed changes. 9. IRB has 10 business days to review the proposed changes and schedule a follow up meeting with the primary researcher.
	Procedure C: Exempted IRB Reviews On occasion, certain research proposals may be exempt from an IRB review where the only involvement of clients is in one or more of the following categories:

	1. The research is conducted in an established or commonly accepted educational setting that involves normal educational practices. 2. Research involves the use of educational tests (cognitive, aptitude, achievement). 3. Research involves the collection or study of existing data, documents, records, that are currently publicly available. 4. The research and demonstration projects are conducted by or subject to the department or agency heads and are designed to study, evaluate, or examine public benefits or service programs, procedures for obtaining benefits or services under those programs, or changes in methods or levels of payment for benefits or services under those programs. 5. Information is recorded by the investigator in a manner that clients cannot be directly identified, or identifiers cannot be linked to the CFSA client.
	Procedure D: Monitoring and Observation CFSA's IRB monitors research proposals by collecting and analyzing data as the project progresses, assuring that the research, its design, and client protections are appropriate.
	Procedure E: Risk Levels Risk is a complex concept that has different meanings in different contexts. Specific risks can be characterized along several dimensions, including the probability of a given harm as well as its likely severity and duration. 1. Before research proposals are approved, the IRB must review the risk levels to determine the safety of the participant. • Risk levels must be determined in accordance with the criteria currently established by federal regulations and international guidelines for research involving clients. 2. Minimal risk includes the probability that the magnitude of harm or anticipated discomfort associated with the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
	Procedure F: Assent and Parental Permission If the IRB requires clients less than 18 years of age to assent to research, the child's assent must be obtained before the child can participate in research activity. For the purpose of this policy "assent" means affirmative agreement to participate in research and applies to clients less than 18 years of age who have not attained the legal age for consent to research. Failure of a client to object should not, absent an affirmative agreement, be construed as assent. Parental permission is required in addition to the child's assent (see *Procedure G*).

1. If assent is required, no researcher can involve a child as a subject in research covered by this policy unless the researcher has obtained assent.

2. If parental rights have not been terminated, parental permission must be obtained and documented before the child can participate in research.

3. One or both parents or guardian must be provided with the information so that they may decide whether to allow their child to participate or to decide whether the child is capable of expressing his or her willingness to participate.

4. Information on the specific research project must be given to the child in the child's primary language and must be written in such a manner as to be understandable to the child and his or her parents or guardian.

5. The IRB may waive the parental permission requirements provided that an appropriate mechanism is in place to protect the child and provided that the waiver is not inconsistent with federal, state, or local law [45 CFR 46.408(c)].

    - An "appropriate mechanism" may include the appointment of a child advocate or assent monitor.

6. In accordance with federal regulations [45 CFR 46.408(a)], the following three types of circumstances allow IRB to consider waiving a child's assent:

    a. Capability of the child is so limited that he or she cannot be consulted.

    b. Intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the child and is available only in the context of the research.

    c. The assent of the child is not a necessary condition for proceeding with the research**.**

Procedure G: Informed Consent

"Informed consent" assures that prospective clients 18 years of age and older understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate, and it minimizes the possibility of coercion or undue influence. Informed consent is required from parents or guardians to allow participation of clients less than 18 years of age who have not attained the legal age for consent (see *Procedure F*). No informed consent, whether oral or written, should include any language that waives or appears to waive any legal rights or releases of a CFSA client, or that appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

1. No researcher may involve a client as a subject in research covered by this policy unless the researcher has obtained the legally-effective informed consent of the client or the client's legally authorized representative.

	2. Under the following circumstances, some or all elements of informed consent may be waived or altered for purposes of an IRB approval: a. The research involves minimal risk to the clients. b. The waiver or alteration must not adversely affect the rights and welfare of the clients. c. The research could not practicably be carried out without the waiver or alteration. 3. Information on the specific research project must be given to the CFSA client in the client's primary language and must be written in such a manner as to be understandable to the client or his or her legally authorized representative.
	Procedure H: Privacy and Confidentiality 1. Before research begins, the IRB should ensure that the researcher has adequately informed CFSA clients that identifiable information that pertains to them will not be divulged to others in ways that are inconsistent with authorized disclosure. 2. All records and information regarding clients in the care of CFSA, including participation in an IRB-approved research project, are confidential [D.C. Official Code § 4-1405(b)]. *See Confidentiality Policy*.