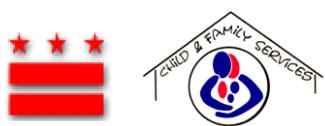


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	CHILD AND FAMILY SERVICES AGENCY Approved by: <u>Rogue Gerald</u> Agency Director Date: <u>September 14, 2010</u>	REVISION HISTORY: October 16, 2002 May 15, 2007
	LATEST REVISION: September 14, 2010	

I. AUTHORITY	The Agency Director adopts this policy to be consistent with the Agency's mission and applicable Federal and District of Columbia laws, rules and regulations including provisions in Title 4, Chapter 13 and title 16, chapter 23 of the DC Code as well as the Department of Health and Human Services (HHS) regulations for the Protection of Human Subjects (Title 45 Code of Federal Regulations, Part 46, and Subpart D; and Title 34 Code of Federal Regulations, Part 97).
II. APPLICABILITY	This policy is applicable to researchers identified as Principal Investigators, as defined by the Office of Human Research Protection (OHRP), the principle investigator is the "scientist or scholar with primary responsibility for the design and conduct of a research project."
III. RATIONALE	The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. Human subject means a living human being from whom an investigator obtains: a) data through intervention or interaction with the subject; or b) identifiable private information (e.g., a clinical record). The IRB is responsible for safeguarding the rights and welfare of all persons participating in research projects, whether funded or non-funded. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by federal regulations. The IRB, however, makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected.
IV. POLICY	In an effort to facilitate and encourage research, the Child and Family Services Agency recognizes the importance of incorporation and utilization of human subjects, particularly in the arena of Human Behavioral Science Research. CFSA also recognizes that the rights of parents are paramount, thus parents shall be contacted prior to allowing any child to participate in a research study. Therefore, it is the policy of the Child and Family Services Agency that Human Behavioral research protocols and proposals be subject to internal agency review by the Child and Family Services Institutional Review Board (hereafter identified as IRB) to ensure that the safety and privacy of utilized human subjects are secured.

	<p>The Child and Family Services Agency IRB is responsible for maintaining balance between the rights of human subjects, the gains of scientific research and societal benefit. The goals for the Child and Family Services Agency IRB are:</p> <ol style="list-style-type: none"> 1. To ensure that the participation of all human subject participants is voluntary; 2. To ensure that the rights and welfare of any such human subject is adequately protected; and 3. To ensure there is an appropriate informed consent process for each human subject.
V. CONTENTS	<ol style="list-style-type: none"> A. IRB Member Composition and Responsibilities B. Initial and Continuing Review of Research Proposals C. Criteria for IRB Research Approval D. Criteria for Provisional Approval E. Criteria for “Tabling” a Proposal F. Criteria for a Disapproved Proposal G. IRB Member Conflict of Interest H. IRB Minutes Content and Documentation I. Research Risks and Levels of Review J. Exempted IRB Reviews K. Expedited IRB Reviews L. Full Board Review M. Informed Consent N. Documentation of Informed Consent, Parental Permission, and Child Assent O. Requirements for Permission by Parents or Guardians and for Assent by Children P. Research involving District of Columbia Wards Q. Selection of Subjects R. Privacy and Confidentiality S. Monitoring and Observation T. Suspension or termination of IRB approval of research
VI. ATTACHMENTS	<ol style="list-style-type: none"> A. IRB Application B. IRB Notification Form
VII. PROCEDURES	<p>Procedure A: IRB Member Composition and Responsibilities</p> <ol style="list-style-type: none"> 1. All research projects shall be reviewed and approved by the CFSA IRB before the research occurs. 2. The CFSA IRB is authorized to approve, request modification of, or disapprove research activities. 3. The CFSA IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

	<p>4. The CFSA IRB is to be comprised of 7 voting members including a chairperson.</p> <p><i>Note: The Chairperson of the IRB shall be the Deputy Director for the Office of Planning, Policy and Program Support (OPPPS) or designee. The IRB members evaluate the work in discussions with the Director of CFSA. In the absence of the IRB Chair, the Deputy Director for OPPPS shall designate signatory authority.</i></p> <p>5. Members of the CFSA IRB must have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the CFSA members whose expertise and experience together constitute an appropriate background for its decisions.</p> <p>6. The CFSA IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.</p> <p>7. The CFSA IRB shall not consist exclusively of members that are of one gender or of one profession.</p> <p>8. The CFSA IRB shall include at least one member whose primary expertise is in scientific areas, at least one member whose primary expertise is in nonscientific areas, and at least one voting member who is not affiliated with CFSA, but who has a research background and/or is a content expert in child welfare.</p> <p>9. A member of the Office of the General Counsel shall be assigned to the IRB for consultation, as may be necessary.</p> <p>10. The CFSA IRB must possess the professional competence necessary to review specific research activities and be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.</p> <p>11. If the CFSA IRB regularly reviews research that involves vulnerable categories of subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.</p>
	<p>Procedure B: Initial and Continuing Review of Research Proposals</p> <p>1. In conducting the initial review of proposed research, the CFSA IRB shall obtain information in sufficient detail to make research determinations.</p> <p>2. Materials must include the full protocol, a proposed informed consent document, any relevant grant application(s), and any recruitment materials, including advertisements intended to be seen or heard by potential subjects.</p>

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	<p>3. In conducting continuing review of research not eligible for expedited review, all CFSA IRB members should at least receive and review a protocol summary and a status report on the progress of the research, including:</p> <ul style="list-style-type: none"> a. The number of subjects accrued; b. A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review; c. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review; d. Any other relevant information, especially information about risks associated with the research; and e. A copy of the current informed consent document and any newly proposed consent document (See Procedure M)
	<p>Procedure C: Criteria for IRB Research Approval</p> <p>1. In order to approve research covered by this policy the CFSA IRB shall determine that all of the following requirements are satisfied:</p> <ul style="list-style-type: none"> a. Risks to subjects are minimized: <ul style="list-style-type: none"> i. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and ii. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research. The CFSA IRB shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. c. Selection of subjects is equitable. In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, LGBTQ youth, prisoners, pregnant women, mentally disabled persons, and/or economically or educationally disadvantaged persons. d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative (See procedure M).

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	<ul style="list-style-type: none"> e. Informed consent will be appropriately documented, in accordance with, and to the extent required by this policy (See procedure M). f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. <p>2. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as: children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the principle investigator must provide additional appropriate safeguards in the study to protect the rights and welfare of these subjects.</p>
	<p>Procedure D: Criteria for Provisional Approval</p> <ul style="list-style-type: none"> 1. The CFSA IRB shall set forth a provisional approval when the proposal requires minor changes that must be rectified within 60 days. The research may not commence until the final approval. Minor changes may include such things as: <ul style="list-style-type: none"> a. Typographical errors; b. Minor re-wording of the consent form; and c. Clarification of methodology. 2. The principle investigator is responsible for addressing the concerns of the IRB before approval can be granted. Once these changes are submitted, the committee, committee chair, or designee (the designee must be designated in writing) may grant approval if the changes are satisfactory. If IRB request(s) are not adequately addressed within 60 days, the proposal must be disapproved and the study must be resubmitted as a new proposal.
	<p>Procedure E: Criteria for “Tabling” a Proposal</p> <ul style="list-style-type: none"> 1. The CFSA IRB will “table” a proposal when there is a need for additional information or clarification of the research issue. The CFSA IRB shall notify the principle investigator in writing indicating the issues being raised. The principle investigator is responsible for addressing the concerns of the IRB before the provisional or final approval can be granted. These changes must be submitted in writing to the CFSA IRB. 2. The proposal will be placed on the agenda for the next scheduled committee meeting upon receipt of the revisions. 3. If the CFSA IRB has not received a response within 60 days of the notification, the proposal will be disapproved and must be resubmitted as a new proposal if it is to be reconsidered for full IRB review.

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	<p>Procedure F: Criteria for a Disapproved Proposal</p> <ol style="list-style-type: none"> 1. A research proposal will be disapproved by the CFSA IRB for any of the following reasons: <ol style="list-style-type: none"> a. The proposal is considered to be lacking key information by which to evaluate its objectives, methods, endpoints, benefits or risks; b. Adequate protection of the research subject is not addressed; c. The risks to the research subject appear to outweigh the benefits of the research study; d. The proposal lacks merit or is designed such that the methodology is unlikely to yield useful data toward meeting the stated objectives; e. CFSA resources are not available to support the proposed research; or f. Other articulable reasons. 2. The CFSA IRB will notify the principle investigator in writing, within 30 days following an IRB decision, outlining the reasons for rejection. The proposal must be revised and resubmitted as a new proposal if it is to be reconsidered for full IRB review.
	<p>Procedure G: IRB Member Conflict of Interest</p> <p>No IRB member may participate in the IRB’s initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. Except when requested by the IRB to be present to provide information, IRB members absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest and such should be noted in the IRB meeting minutes.</p>
	<p>Procedure H: IRB Minutes Content and Documentation</p> <p>CFSA, or when appropriate the IRB, must prepare and maintain adequate documentation of IRB activities. Such documentation must include copies of all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects.</p> <ol style="list-style-type: none"> 1. Minutes of IRB meetings shall be kept in sufficient detail to record the following information: <ol style="list-style-type: none"> a. Attendance at each meeting; b. Actions taken by the IRB; c. The vote on all IRB actions including the number of members voting for, against and abstaining. In order to document the continued existence of a quorum, the CFSA IRB follows the Office of Human Research Protection’s recommendation that votes recorded in the minutes use the following format: Total = 15; Vote: For – 14, Opposed – 0, Abstained – 1; d. The basis for requiring changes in or disapproving research;

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	<ul style="list-style-type: none"> e. A written summary of the discussion of controverted issues and their resolution; f. Separate deliberations, actions and votes for each proposal undergoing initial or continuing review by the convened IRB; g. Comments of IRB members, whether for or against the majority vote; and, h. Whether the IRB determines which research proposals require continuing review more often than annually as appropriate to the degree of risk. The minutes shall clearly reflect these determinations regarding risk and approval period. <p>2. The CFSA IRB records shall be retained for at least 3 years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services at reasonable times and in a reasonable manner.</p>
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	<p>Procedure I: Research Risks and Levels of Review</p> <p>The CFSA will only be approving research that presents “low-risk” or “minimal risk” to human subjects. The CFSA IRB will not approve research involving pharmaceutical or biomedical devices. The CFSA IRB will use the following risk categories to determine the appropriate level of review:</p> <p>1. <i>“Low-Risk” Research Without Identifying Information (Less Than “Minimal Risk”)</i></p> <ul style="list-style-type: none"> a. This category refers to research in which the researcher will not contact the human subject in person, but may request access to client or employee data maintained by the Agency or its contractors, that contains no identifying information and the risk of harm or discomfort to the human subject is less than minimal. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are 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. b. The following research may be considered “low-risk without identifying information”: <ul style="list-style-type: none"> • The researcher reviews client or employee data, databases or aggregate data that contain no information by which an individual subject can be identified. c. Review requirements: <ul style="list-style-type: none"> • All “low-risk without identifying information” research requires Agency approval and assurances that the researcher has made adequate provisions to safeguard data and to comply with all local and Federal regulations, which specifies when the Agency may allow access to “private” or “controlled” records for research purposes.
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	<p>2. <i>“Low-Risk” Research With Identifying Information (Less Than “Minimal Risk”)</i></p> <p>a. This category refers to research in which the researcher will not contact the human subject in person, but may request access to client or employee data maintained by the Agency or its contractors, that contains identifying information and the risk of harm or discomfort to the human subject is less than minimal.</p> <p>b. The following research may be considered “low-risk with identifying information”:</p> <ul style="list-style-type: none"> • The researcher reviews client or employee data or databases that contain the clients’ or employees’ names or other identifying information with no contact to the client or employee. <p>c. Review requirements:</p> <p>i. The researcher has made adequate provisions for soliciting informed consent of human subjects, permission of their parents or guardians, and the informed assent of children or from subjects who suffer from some mental incapacity, when applicable. (See procedures M, N and O.)</p> <p>ii. All “low-risk with identifying information” research requires Agency approval and assurances that the researcher has made adequate provisions to safeguard data and to comply with all local and Federal regulations, which specifies when the Agency may allow access to “private” or “controlled” records for research purposes.</p> <p>iii. If “low-risk with identifying information” research is conducted by an outside researcher, including an Agency employee doing research outside the scope of their employment, the research proposal must be approved by the CFSA IRB.</p> <p>iv. Research involving children does not qualify for exemption from review except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.</p> <p>3. <i>“Minimal Risk” Research</i></p> <p>a. This category refers to research that involves <i>intervention or interaction</i> with the human subject when the probability and magnitude of harm or discomfort that the researcher anticipates will be experienced by the human subjects are 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.</p> <p>b. This category may also include research that does not require interaction, such as research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).</p>
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	<p>c. Review requirements:</p> <ul style="list-style-type: none"> i. All research in this category requires CFSA IRB expedited review as a minimum (see procedure K), and prior <i>review of methodology</i> and letter of support from the appropriate CFSA IRB representative, regardless of whether the research is conducted by an Agency employee or an outside researcher. ii. The researcher has made adequate provisions for soliciting informed consent of human subjects, permission of their parents or guardians, and the informed assent of children or from subjects who suffer from some mental incapacity, when applicable. (See procedures M, N and O.) <p>4. <i>Research Involving Greater Than Minimal Risk to the Human Subjects, But Providing Some Direct Benefit to the Subjects</i></p> <ul style="list-style-type: none"> a. This category refers to research that involves <i>intervention/interaction</i> with the human subject for treatment or survey purposes when the subject’s anticipated harm or discomfort involves a greater-than-minimal risk and when the intervention presents the prospect of direct benefit to the individual subject. b. Review requirements: <ul style="list-style-type: none"> i. All research in the “greater-than-minimal risk, but providing some direct benefit to the subjects” category requires full CFSA IRB review, and prior <i>review of methodology</i> and letter of support from the appropriate CFSA IRB representative. ii. The researcher must assure that informed consent requirements are met and that where applicable, informed assent requirements for children are met. (See Procedures M, N and O.) c. The CFSA IRB may approve research involving a greater-than-minimal risk only if its review finds that the: <ul style="list-style-type: none"> i. Proposed intervention or procedure holds out the prospect of direct benefit for the individual subject, or the intervention or procedure involves a monitoring procedure that is likely to contribute to the subject's well-being; ii. Risk is justified by the anticipated benefit to the human subjects; iii. Relation of the anticipated benefit to the risk is at least as favorable to the human subjects as that presented by available alternative approaches; and iv. Researcher has made adequate provisions for soliciting informed consent of human subjects, permission of their parents, the GAL and the informed assent of children or from clients who suffer from some mental incapacity, when applicable.
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	<p>5. Research Involving “Greater-Than-Minimal Risk” and No Direct Benefit to the Human Subjects, but Likely to Yield Generalizable Knowledge about the Subject's Disorder or Condition</p> <p>a. This category refers to research that involves a greater-than-minimal risk by an intervention or procedure that does not hold out the prospect of direct benefit to the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, but is likely to yield generalizable knowledge about the subject's disorder, condition, or the programs designed to assist or ameliorate the subject's disorder or condition.</p> <p>b. Review requirements:</p> <ul style="list-style-type: none"> i. All research in the “greater-than-minimal risk” with no direct benefit to subject category requires full CFSA IRB review, and prior <i>review of methodology</i> and letter of support from the appropriate CFSA IRB representative. ii. The researcher must assure that informed consent requirements are met and that where applicable, informed assent requirements for children are met. (<i>See Procedure O</i>) <p>c. The CFSA IRB may approve research in this category only if its review finds that the:</p> <ul style="list-style-type: none"> i. Risk represents a minor increase over minimal risk; ii. Intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; iii. Intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition (except in research involving children); iv. Intervention or procedure is likely to yield generalizable knowledge about the understanding of the programs designed to ameliorate the subjects' disorder or condition; and v. Generalizable and/or program benefits outweigh the risks to subjects. <p>6. Studies Involving Greater-Than-Minimal Risk, with No Benefit to the Human Subject, nor Generalizable or Program Knowledge</p> <p>If the proposed research study involves more than minimal risk to the human subject, with no prospect of direct benefit to the individual subjects, and the study is not likely to yield generalizable knowledge about the subject's disorder or condition or the programs designed to serve the subject population, the Agency will not review nor approve the study, regardless of whether the researcher is an Agency employee or an outside researcher.</p>
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	<p>Procedure J: Exempted IRB Reviews</p> <p>Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt:</p> <ol style="list-style-type: none"> 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: <ol style="list-style-type: none"> a. research on regular and special education instructional strategies; or b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the information identifies the subjects and disclosure could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. 3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. If these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. 4. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine include: <ol style="list-style-type: none"> a. Public benefit or service programs; b. Procedures for obtaining benefits or services under those programs; c. Possible changes in or alternatives to those programs or procedures; or d. Possible changes in methods or levels of payment for benefits or services under those programs.
	<p>Procedure K: Expedited IRB Reviews</p> <p>As defined, an expedited review is a review of proposed research by the CFSA IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving low risk approved research.</p> <p>A risk is low where the probability and magnitude of harm or discomfort anticipated in the proposed research are 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.</p> <ol style="list-style-type: none"> 1. An expedited IRB review is applicable where research activities: <ol style="list-style-type: none"> a. Present no more than low risk to human subjects; and

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	<p>b. Involve only procedures listed in one or more of the categories listed in Procedure J 2. The activities listed should not be deemed to be of low risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than low risk to human subjects.</p> <p>2. List of categories include the following:</p> <p>a. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.</p> <p>b. Collection of data from voice, video, digital, or image recordings made for research purposes.</p> <p>c. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.</p> <p>d. Continuing review of research previously approved by the convened IRB as follows:</p> <p>i. The research is permanently closed to the enrollment of new subjects;</p> <p>ii. All subjects have completed all research-related interventions;</p> <p>iii. The research remains active only for long- term follow-up of subjects;</p> <p>iv. Where no subjects have been enrolled and no additional risks have been identified or;</p> <p>v. Where the remaining research activities are limited to data analysis.</p> <p>3. The above mentioned categories apply regardless of the age of subjects.</p> <p>4. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than low.</p> <p>5. The expedited review procedure may not be used for classified research involving human subjects.</p> <p>6. Standard requirements for informed consent apply regardless of the type of review--expedited or convened--utilized by the IRB.</p>
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	<p>Procedure L: Full Board Review</p> <p>Review of proposed research at a convened meeting at which a valid quorum (4 members) of the CFSA IRB members is present. For research to be approved, it must receive the approval of a majority of those members present.</p> <p>At the discretion of the IRB Chair, meetings and reviews may be convened via conference call, may be web-based, and/or by other communication means. The rules on quorum and approval of the research, as stated above, remain applicable.</p>
	<p>Procedure M: Informed Consent</p> <p>Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or in the case of minor subjects, the permission of the subject's parent/legal guardian. The investigator shall also obtain the minor subject's assent to participate in the study when appropriate. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.</p> <ol style="list-style-type: none"> 1. Basic elements of informed consent. Except as provided in paragraph 2 or 3 of this section, in seeking informed consent the following information shall be provided to each subject: <ol style="list-style-type: none"> a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; b. A description of any reasonably foreseeable risks or discomforts to the subject; c. A description of any benefits to the subject or to others which may reasonably be expected from the research; d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

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	<p>h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.</p> <p>2. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:</p> <p>a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;</p> <p>b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;</p> <p>c. Any additional costs to the subject that may result from participation in the research;</p> <p>d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;</p> <p>e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and</p> <p>f. The approximate number of subjects involved in the study.</p> <p>3. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:</p> <p>a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:</p> <ul style="list-style-type: none"> i. public benefit or service programs; ii. procedures for obtaining benefits or services under those programs; iii. possible changes in or alternatives to those programs or procedures; or iv. possible changes in methods or levels of payment for benefits or services under those programs; and <p>b. The research could not practicably be carried out without the waiver or alteration.</p> <p>4. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:</p> <p>a. The research involves no more than minimal risk to the subjects;</p>
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	<ul style="list-style-type: none"> b. The waiver or alteration will not adversely affect the rights and welfare of the subjects; c. The research could not practicably be carried out without the waiver or alteration; and d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. <p>5. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.</p> <p><i>Note: Informed consent shall be communicated in the participant's primary language.</i></p> <p>6. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.</p> <p><i>Note: See also Procedure N and O.</i></p>
	<p>Procedure N: Documentation of Informed Consent, Parental Permission, and Child Assent</p> <p>Informed consent shall be documented by the use of a written consent form approved by the CFSA IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.</p> <ul style="list-style-type: none"> 1. The consent form may be either of the following: <ul style="list-style-type: none"> a. Written consent document that embodies the elements of informed consent required by procedure M. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or b. Short form written consent document stating that the elements of informed consent required by procedure M have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the CFSA IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

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	<p>2. The CFSA IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:</p> <ul style="list-style-type: none"> a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern or; b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. <p><i>Note: In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.</i></p> <p>3. Permission by parents or guardians shall be documented in accordance with the informed consent documentation procedure outlined above. CFSA IRB may find that waiver of documentation of informed consent is appropriate under certain circumstances.</p> <p>4. The CFSA IRB may waive the requirements for obtaining parental or guardian permission if it makes and documents the findings under either <u>45 CFR 46.116(c) or (d)</u>. Additionally, if the CFSA IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the parental permission requirements provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent with federal, state, or local law (<u>45 CFR 46.408(c)</u>). The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status.</p> <p>5. Formal documentation of child assent is not required. However, CFSA IRB has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, CFSA IRB will decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent.</p> <p>If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. CFSA IRB may also decide that documentation of assent is not warranted.</p>
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	<p>6. Waiver of Child Assent. CFSA IRB is responsible for deciding whether child assent is required in proposed research activities. CFSA IRB should require child assent unless it can be appropriately waived, or if the child is not capable of providing assent.</p> <p>The regulations at 45 CFR 46.408(a) identify three types of circumstances where the IRB may determine that waiver of children's assent is appropriate if the:</p> <ol style="list-style-type: none"> a. Capability of some or all of the children is so limited that they cannot reasonably 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 children and is available only in the context of the research. c. Research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either <u>45 CFR 46.116(c) or 45 CFR 46.116(d)</u>. <p>7. Consent forms, assent forms, and documented contacts will then be sent to the CFSA IRB Chairperson to be stored with the research proposal.</p> <p><i>Note: See also Procedure M and O.</i></p>
	<p style="text-align: center;">Procedure O: Requirements for Permission by Parents or Guardians and for Assent by Children</p> <ol style="list-style-type: none"> 1. In general, one or both parents or a guardian must be provided with the information ordinarily required for informed consent, so that they may decide whether to allow the child to participate, and children capable of assent must also express their willingness to participate. 2. The CFSA social worker for the child shall determine if the child will be available and ready to participate in the proposed research. The social worker shall inform the researcher that the child is available for the proposed research. 3. If the child is under 18 years of age and the parental rights have not been terminated, the parent(s) must be consulted and give their permission for the child to participate. The parent(s) shall be given ten (10) days to respond to the request to participate. At least one (1) parent must sign the consent form. 4. If the child is under 18 years of age and the parental rights have been terminated, the GAL and Special Interest Attorney (if one is appointed for the child) must be consulted and together may give consent for the child to participate in the research.

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	<p>5. If the social worker determines that the child has the maturity to understand the implications of participating in research, they must be consulted about their potential participation. It must be explained that participation is voluntary, if they do not assent it will not in any way affect services they or their families receive from Child and Family Services Agency or a contracted agency, and if they do assent they can withdraw from the research project at any time without penalty. Evaluation of the child's level of maturity is done by the child's assigned social worker based on previous information provided from collateral contacts. If the child agrees to participate, he or she shall sign an informed consent form. If the child does not agree he or she cannot participate in the research.</p> <p>6. If the research involves an issue which the child can give consent outside the research context, regardless of age, under applicable state and local laws (for example, research on sexually transmitted diseases or pregnancy), then the child's informed consent is required (regardless of age).</p> <p>7. If the research is minimal risk or greater (<i>see procedure I</i>), the Guardian ad Litem (GAL) must be consulted. The GAL must be given a description of the research project. The GAL must consent in writing. They need to be provided the anticipated start date for the research. They also need to be provided a date by which response is required so that they can express any concerns they have prior to then. The GAL must be given at least 10 days to review and respond to the research proposal. Contact with the GAL must be documented for each child.</p> <p>8. Permission to participate shall be in writing from the parent, the GAL and the child (as applicable) and shall be documented in accordance with procedure M.</p> <p><i>Note: See also Procedure M and N.</i></p>
	<p>Procedure P: Research involving District of Columbia Wards</p> <p>1. As set out in <u>45 CFR 46.409</u>, before children who are wards of the District of Columbia or any other agency, institution, or entity can be included in research, the research must meet the following conditions:</p> <ol style="list-style-type: none"> the research must be either related to the children's status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards; and the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis.

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	<ol style="list-style-type: none"> 2. One individual may serve as advocate for more than one child, and must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research. The advocate should represent the individual child subject's interests throughout the child's participation in the research. This added protection is intended to ensure that the ward, who is particularly vulnerable, is not exploited, coerced, or subjected to undue influence or harm in the course of the research. The advocate can be the child's social worker. However, the advocate cannot be associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization. 3. If the research is greater than minimal risk, the appointed Guardian ad Litem (GAL) must be contacted. The GAL representing the child must be given a description of the research project. If the GAL expresses concerns regarding the child's participation in the research, the child cannot participate. The GAL may be contacted via phone or certified mail. They need to be provided the anticipated start date for the research. They also need to be provided a date by which response is required so that they can express any concerns they have prior to then. The GAL must be given at least 10 days to review and respond to the research proposal. Contact with the GAL must be documented for each child.
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	<p>Procedure Q: Selection of Subjects</p> <ol style="list-style-type: none"> 1. Appropriate group of subjects for a research project involves the following factors: <ol style="list-style-type: none"> a. Requirements of scientific design; b. Susceptibility to risk; c. Likelihood of benefit; d. Practicability and; and e. Considerations of fairness. 2. The CFSA IRB shall make the determination that the selection of research subjects is equitable. 3. The CFSA IRB will closely review the selection of subjects to ensure the following: <ol style="list-style-type: none"> a. That the nature of the research requires or justifies utilization of the proposed population; b. That anticipated benefits to the subjects are distributed fairly; c. That no risks are likely by identification of physiological, psychological or social characteristics; and d. If the subjects are susceptible to pressures, there are mechanisms by which to reduce or minimize the impact.
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	<p>Procedure R: Privacy and Confidentiality</p> <p>CFSA is a child-placing agency. As such, all records regarding children in CFSA's care and all facts learned about those children, and their parents or relatives, are confidential. D.C. Official Code §4-1405(b). (See CFSA's policy on Confidentiality.)</p> <p>Before the onset of research, subjects should clearly understand that confidentiality pertains to the treatment of any and all information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.</p> <p>In doing so, the CFSA IRB will ensure privacy and confidentiality of research subjects in the following ways:</p> <ol style="list-style-type: none"> 1. Research does not involve observation or intrusions in situations where subjects have a reasonable expectation of privacy; 2. Adequate provisions have been made for protecting the confidentiality of data through coding, destruction of identifying information and limited access to data; and 3. The principle investigator's disclosures to subjects about confidentiality are adequate.
	<p>Procedure S: Monitoring and Observation</p> <p>The CFSA IRB will monitor the research proposal by the collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.</p> <p>The CFSA IRB will ensure monitoring of each research proposal by reviewing:</p> <ol style="list-style-type: none"> 1. The proposed ways in which the data is to be recorded and maintained; and 2. Research adequacy in terms of timeliness and thoroughness.
	<p>Procedure T: Suspension or Termination of IRB Approval of Research</p> <p>The CFSA IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Agency Director.</p>

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**The Child and Family Services Agency
Institutional Review Board (IRB)**
400 6th Street, SW, Washington, DC 20024
Phone: 202-7247100 Fax: 202-727-5619

**ATTACHMENT A
CFSA IRB REVIEW APPLICATION**
Authority: Code of Federal Regulations Title 45 Part 46

Completion of Sections 1-5 is mandatory for all applications. Note: To complete this application, type answers directly into shaded answer areas. To check a box, put your cursor on the box, double click and choose “checked.”

SECTION 1 – PROJECT IDENTIFICATION (completion of this section is mandatory)

- 1.1 Title of the Project** (title must be the same on all study documents):
- 1.2 Principle Investigator** (“scientist or scholar” with primary responsibility for the design and conduct of the research project)
- 1.3 Principle Investigator’s Signature:** (required to assure responsibility for the protection of human subjects and adherence to the CFSA IRB requirements):

- 1.4 Principle Investigator’s affiliated institution:**
- 1.5 Point of Contact** (CFSA employee responsible for the Agency’s role in this research):
- 1.6 Source of Funding** (include both the name and type of agency, e.g., CDC-federal):
- 1.7 Grant Number (REQUIRED)** for all federally funded projects):
- 1.8 Project Type** (Check all that apply)
 - Direct human subject participation involving invasive treatments, procedures, or experimentation.
 - Direct human subject participation using surveys, interviews, focus groups, observations, etc.
 - Indirect human subject participation using human data that was collected, or will be collected, from non research purposes.
- 1.9 What is the projected date to begin this research?**
- 1.10 What is the projected date to complete this research?**
- 1.11 List any other IRBs that will or have reviewed this project:**
- 1.12 Describe any potential conflicts of interest between the researchers and the study sponsors:**

*****END OF SECTION 1*****

SECTION 2 – APPLICATION TYPE (completion of this section is mandatory)

2.1 Does the research involve direct human subject participation? YES NO

If YES, complete Sections 1-10.
If NO, skip to 2.2.

- Surveys, interviews, focus groups, observations, etc. – **complete also Section 11.**
- Project will use existing human-derived data previously collected or to be collected in the future for non research purposes – **complete also Section 15.**

2.2 Does the research involve only indirect human subject participation? YES NO

If YES, complete Sections 1-5 AND Section 11.

*****END OF SECTION 2*****

SECTION 3 – RESEARCH INFORMATION (completion of this section is mandatory)

3.1 Provide a concise (300 words) summary of the research, including the following information:

FOR RESEARCH THAT INVOLVES DIRECT HUMAN SUBJECT PARTICIPATION

- Age, gender, ethnicity, and race distribution of the study population, including vulnerable populations
- What will be done to the participants for research purposes
- Whether or not the research records will be linkable in any way to the research participants
- Informed consent process to be employed

FOR RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

- Information on the kind and source of data
- What will be done with data
- How data will be linkable to the persons from whom the data is derived
- Informed consent process to be employed

(Type 300 word summary here)

3.2 What documents are you submitting with this application? Check only those that are applicable.

- Study protocol
- Informed consent instrument(s)
- Investigator’s brochure, solicitation materials for subject recruitment (specify):
- Survey instruments
- HIPPA-Compliant Request Form for waiver of authorization
- IRB review/approval documents from institution of principal investigator, if not CFSA
- Other (specify):

3.3 If you believe that this project qualifies for one of the exemptions in CFSA’s IRB policy please indicate here the specific exemption:

*****END OF SECTION 3*****

SECTION 4 – INFORMED CONSENT PROCESS (completion of this section is mandatory)

4.1 Check the type(s) of informed consent process that will be used? Check all that apply.

- A comprehensive written document, signed by the participant (or legal representative).
- A comprehensive written document, that is not signed (justify with criteria in 46.117(c)).
- A short written document stating that all required elements have been presented orally to the participant (or legal representative) and signed by either of them (justify with criteria in 46.117(c)).
- The assent of children that documents their willingness to participate in research (required from children who are capable of comprehending the nature of the study).
- Check this box if you are asking not to use one of these standard informed consent processes and complete “4.2” below.

4.2 Check the appropriate box below if you will not use a standard informed consent process or if you do not plan to seek consent.

- Check this box to request to alter or waive the informed consent requirement in whole or in part. (The IRB may approve research that alters, some or all of the required elements of informed consent or waives the requirement for consent entirely. The provisions of 46.116** (that permit these exceptions must be explained when such exceptions are requested.) Please specify what waiver or alteration you are requesting and how your project satisfies each of the criteria in 46.116.
- Check this box if you are requesting a waiver of authorization to disclose “protected health information” under HIPAA for research purposes. If yes, please attach a HIPAA-compliant request for waiver of authorization.
- Check this box if you believe that informed consent is unnecessary because your project can be exempted as explained in 3.3 of this application.

4.3 Submit texts of all project-specific informed consent instruments for approval by the CFSA IRB and indicate what consent documents are appended.

4.4 Check below who may act on behalf of the subject to give consent to participate in this research.

Check all that apply.

- The adult participant in the research himself/herself
- The legal guardian of the participant in the research
- The next-of-kin of an adult participant (specify relationship):
- One parent of a child who participates in the research
- Only** both parents of a child who participates in the research
- The assent of a child who participates in the research

4.4 Specify the criteria to be used to determine whether or not assent to participate should be obtained if children are among the research participants.

Consult 45 CFR 46.116 and 46.117 – for guidance on the elements of informed consent.

Information must be presented in a manner that will enable someone to voluntarily decide whether or not to participate in the research. For assistance in preparing informed consent documents, please see “[Guidelines for Informed Consent](#)” located on the HHS website.

The informed consent process requirements are found in 45 CFR 46.116 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>) and the documentation of informed consent requirements in 45 CFR 46.117 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117>).

Informed consent is a process to protect the rights of human research participants and it should not be considered primarily a form to protect the researcher.

*****END OF SECTION 4*****

Sections (5-10) Are For Research That Involves Direct Human Subject Participation

SECTION 5 – CHARACTERISTICS OF HUMAN PARTICIPANTS

(Leave this section blank only if there is no direct human participation in the research)

5.1 What health/disease categories (e.g. health participants, diabetics, etc.) are involved?

5.2 How many participants in each health/disease category will be recruited?

5.3 What will be the total duration of involvement of a participant in the study?

5.4 Describe if the research involves a health problem that may be relevant to certain populations.

5.5 Provide justification for research limited to a particular age, gender, or ethnic or racial group.

5.6 Check which of the following vulnerable populations may be research participants?

- None
- Children (age <18 years)
- Mentally compromised or decisionally impaired persons (specify)
- Women with child-bearing (reproductive) potential
- Pregnant or lactating women
- Prisoners

5.7 Check which of the following populations that could be subject to coercion may be among the participants?

- None
- Economically (coercion may result from payments to participants) or educationally deprived
- Patients of the investigator

- Students of the investigator
- Employees of the investigator

5.8 Unless incidental, justify the inclusion of research participants considered vulnerable or susceptible to coercion.

5.9 What are the criteria for inclusion, and exclusion, of research participants?

*****END OF SECTION 5*****

SECTION 6 – PARTICIPANT RECRUITMENT PROCEDURES

(Leave this section blank **only** if there is no direct human participation in the research).

6.1 How (e.g., existing list, random) will potential research participants be identified for recruitment?

6.2 Where (e.g., at home, in a clinic) will the potential research participants be recruited?

6.3 How (e.g., phone call, brochure, letter) will the potential research participants be recruited?

6.4 If recruitment materials (e.g., advertisements, letters) are to be used, are they attached? YES
 NO

6.5 If the research involves a health problem that may have specific relevance to certain ethnic, racial, or other minority groups, what special measures will be taken to optimize recruitment of participants from these groups?

*****END OF SECTION 6*****

SECTION 7 – RISKS AND BENEFITS OF THE RESEARCH

(Leave this section blank **only** if there is no direct human participation in the research).

7.1 To indicate your judgment of the overall research-related risk of harm to participants, choose ONE of the three levels below

- Low Risk
- Minimal risk *
- Moderate risk
- High risk

* A minimal risk is considered one where the probability and magnitude of harm or discomfort anticipated in the research is not greater, in and of itself, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

7.2 What direct risks could participants face by participating in this research, and what measures will be taken to minimize each risk?

7.3 If “vulnerable populations” or populations susceptible to coercion are among the research participants, what additional measures will be taken to minimize risks that may affect them?

7.4 What indirect risks (if any) to the public or community could result from this research?

7.5 What potential direct benefits (if any) could this research provide participants?

7.6 What potential indirect benefits could this research provide the public or others?

*****END OF SECTION 7*****

SECTION 8 – RESEARCH RECORDS

(Leave this section blank **only** if there is no direct human participation in the research).

- 8.1 Will research records be linkable to the participants by any identifiers, including names, registration numbers, code numbers, etc., entered into the records? YES NO (If NO, skip to 8.3)
- 8.2 If information in the research records was revealed, could it place the participants (or others) at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation? YES NO
- 8.3 Describe the procedures that will be taken to ensure the privacy of the participants and to preserve the confidentiality of private information, including any plans to seek a “Certificate of Confidentiality” or “Director’s Medical Research Project” designation. (Privacy is the right of an individual to control his or her personal information whereas confidentiality is the obligation of the researcher to protect private information they receive).

*****END OF SECTION 8*****

SECTION 9 – COSTS OF THE RESEARCH

(Leave this section blank **only** if there is no direct human participation in the research).

- 9.1 Describe any and all costs that the participant could incur by their participation, including indirect costs such as insurance.

*****END OF SECTION 9*****

SECTION 10 – INTERVIEWS, SURVEY OR GROUP MEETINGS INVOLVING THE RESEARCH PARTICIPANTS

- 10.1 Describe the methods that will be used to collect information relevant to this section.
- 10.2 What is the anticipated duration and number of the sessions to collect this information?
- 10.3 Describe the information that will be collected by interview, survey, or group meetings.
- 10.4 If information will be collected by telephone, explain the consent procedure.
- 10.5 How will the privacy of the participants be protected while collecting information?
- 10.6 Could revelation of collected information place the participant, or others, at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation? YES NO If YES, explain.
- 10.7 How will the information be recorded? Check all applicable entries.
- Text entered by investigators
- Text entered by the subject
- Voice of the subject
- Image of the subject
- Other (specify):
- 10.8 Describe how any survey records (instruments, recordings, etc.) will be labeled or identified to provide a direct, or indirect link, to the participant.
- 10.9 Are survey instruments and letters of prior announcement of intent to contact attached? YES NO

*****END OF SECTION 10*****

SECTION 11 – RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

Complete this section for research that uses: a) existing human data that were collected previously for a purpose other than this research, or b) human data that will be collected in the future for non research purposes.

(Please note that if the research involves both direct human subject participation and also a component that does not involve direct human subject participation, you must complete both the appropriate sections of 5-10).

- 11.1 State why and how the existing data was collected, or how data to be used in this research will be collected for non research purposes.
- 11.2 Was the existing data originally stored in a way that could reveal the identity of the person from whom the data originated? YES NO (If NO skip to the checklist on page 9).
- 11.3 Will the research records carry any identifiers that could link the information to the person, from whom the data originated? YES NO (If NO skip to the checklist on page 9).
- 11.4 What type of data will be used for research?
- 11.5 From how many persons did/will the data originate?
- 11.6 From what source(s) will the data be procured?
- 11.7 How will the investigators gain access to the data?
- 11.8 If the data was originally collected for non research purposes, have the persons from whom the data originated agreed that the data might also be used for research purposes? YES NO
- 11.9 Does use of the data involve information which, if revealed, could place someone at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation? YES NO
- 11.10 How will the permission of the persons from whom the data originated be obtained to use the data for research purposes?
- 11.11 What measures will be taken to keep the research records confidential?
- 11.12 Describe any access that researchers will have to information that is not essential to the research, what will be done with this non essential information, and how it will be protected?
- 11.13 Could the research to be conducted on the data reveal information of potential benefit to the persons from whom the data originated? YES NO If YES, describe plans to inform participants about their rights:
- 11.14 Could the research lead to the development of a commercial product that may bring financial benefit to the investigators and/or the sponsor? YES NO If YES, describe plans to inform participants about their rights:

*****END OF SECTION 11*****

CFSA IRB REVIEW REQUEST COMPLETENESS CHECKLIST

Completion of this section is mandatory. Numbers in parentheses refer to the sections of the application, where the corresponding issues appear.

For each item shown in the following list the applicant should check off the cell to the left of each applicable item to indicate that it has been carried out and/or submitted. The column to the right is for the CFSA IRB use only.

Investigator Completes		CFSA IRB
<input type="checkbox"/>	Documents are dated to indicate the latest revisions.	
<input type="checkbox"/>	The same project title is on the application, the study protocol and the informed consent documents.	
<input type="checkbox"/>	Name of the Principle Investigator is shown.	
<input type="checkbox"/>	Principle Investigator's signature appears on printed copies (1.2).	
<input type="checkbox"/>	Printed copies of all project-specific consent instruments submitted (3.2, 4.2)*.	
<input type="checkbox"/>	Date of most recent version of consent document is shown.	
<input type="checkbox"/>	Printed copies of survey instruments submitted (3.2, 10.9)*.	
<input type="checkbox"/>	Printed copy of Study Protocol submitted (3.2)*.	
<input type="checkbox"/>	Printed copies of solicitation materials for subject recruitment submitted (3.2, 6.4)*.	
* Indicates these documents are required when these sections of the application form apply		

FOR CFSA IRB OFFICE USE ONLY:

Date Submitted:		Processed by:	
Decision final:			
Notice sent:		Review time:	

The Child and Family Services Agency is an equal opportunity employer, services, and programs provider.



**Child and Family Services Agency
Institutional Review Board (IRB)**

**ATTACHMENT B
IRB Notification Form**

Principal Investigator: _____

Co-Investigators: _____

Title: _____

Approved

Approved with conditions

Disapproved

Comments:

1. You are required to immediately report any adverse reactions or complications of the project to the CFSA IRB.
2. There may be no change or addition to the project, or changes of the investigators involved, without prior approval of the CFSA IRB.
3. If applicable, the attached consent statement has been approved by the CFSA IRB. Please copy this document and use for all subjects entered into this study.

Chairperson, Institutional Review Board

Date