GOVERNMENT OF THE DISTRICT OF COLUMBIA
Child and Family Services Agency

Business Process: Institutional Review Board

I. Policy

It is the policy of Child and Family Services Agency ("CFSA" or "Agency") to protect the safety and privacy of any CFSA client involved in human behavioral research protocols and proposals. This protection is ensured through an internal Agency review by CFSA's Institutional Review Board ("IRB"). The *Institutional Review Board* policy is available on the CFSA website as well as the Agency's intranet.

II. Procedures

A. IRB Membership and Responsibilities

The following guidelines apply to the selection and responsibilities of IRB members:

1. At a minimum, the IRB voting membership should comprise of five individuals:
   a. A chairperson
   b. At least one external stakeholder (i.e., non-CFSA employee)
   c. A member with primary expertise in a scientific area
   d. A member with a research background or content expertise in child welfare
   e. A representative from CFSA's Office of the General Counsel

2. IRB meetings are called by the chairperson every six months or whenever proposals are submitted. The chairperson or his or her designee chairs the meeting.

3. An IRB member documents Board activities and discussions that take place in the meetings.

4. The IRB must prepare and maintain adequate documentation of IRB activities including copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, reports of injuries to subjects, correspondence, approvals or disapprovals, records of review activities, a list of IRB members, IRB policies and written procedures, etc. IRB records must be retained for at least three years. Records relating to research which is conducted must be retained for three years after completion of the research.

5. Documentation of meeting minutes should include the following information:
   a. Attendance of a quorum of four members at each decision-making meeting
   b. Record of decisions and votes, including the number of members voting for, against, or abstaining from decisions concerning each individual proposal
      - Meeting minutes will record votes according to the following sample format recommended by the federal Office for Human Research Protections:

        Vote: For-14, Opposed-0, Abstained-1; Total=15
   c. Determinations regarding risk (see Risk Levels) and approval of proposals

d. Justification for any changes or rejections of individual research proposals

e. Summary of any discussion regarding controversial issues, including resolutions or lack thereof related to each proposal

f. Status of proposals that might require reviews more often than annually, based on the degree of risk to participants

g. Attachments as applicable (e.g., signed consent forms, supportive documents, or other relevant materials)

B. IRB Review of Proposal Application

1. Before investigators begin their research project, they must first submit an IRB *Proposal Application* (*see Attachment A)*

2. Once the research investigator completes the proposal application, which should include a schedule for submitting status reports on the research project, the investigator submits the application to the CFSA IRB chairperson, the Deputy Director for the Office of Policy, Planning, and Program Supports.

   - The proposal application may be faxed to (202) 727-5015, or mailed to the attention of the IRB chairperson at 200 I Street, SE, Washington DC, 20003, Room 3224.

3. Within two business days of receipt of the application, the IRB chairperson sends a copy of the proposal to each IRB member.

4. Each IRB member has 10 business days to complete their review of the application.

5. After the members have completed their reviews, the IRB has 10 business days to meet, discuss, and finalize their decision.

6. The IRB notifies the principal investigator and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it must include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

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.

10. When reviewing research proposals, IRB members determine whether the following requirements are satisfied:

    a. Risks to clients are minimized through the following steps:

       i. Procedures are consistent with sound research design

       ii. Whenever appropriate, procedures have already been used for diagnostic or treatment purposes

    b. The research plan adequately provides for the monitoring of collected data as well as monitoring the safety of research participants

c. Adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data

d. Informed consent and assent is documented from each prospective participant or his or her legally authorized representative

11. Upon review of the proposal, IRB members may reject the research for one or more of the following reasons:
    a. The proposal lacks sufficient information for IRB members to evaluate its objectives, methods, endpoints, benefits, or risks
    b. Adequate protection of the client is not addressed
    c. The risks to the client appear to outweigh the benefits of the research
    d. The research or methodology is unlikely to yield data useful toward the stated objectives
    e. CFSA resources are not available to support the proposed research

12. Expedited reviews (i.e., the entire process is completed within 10 business days) may be considered under the following circumstances:
    a. The proposal presents either low risk or no risk to the clients (*see Section D: Risk Levels*)
    b. The type of research falls into one or more of the following categories:
        i. The research materials (e.g., data, documents, records, or specimens) are collected or will be collected solely for non-research purposes
        ii. Data collection uses only voice, video, digital, or image recordings that have been designed for research purposes
        iii. The following methodologies are employed:
            a) Surveys
            b) Interviews
            c) Oral histories
            d) Focus groups
            e) Program evaluations
            f) Human factors (evaluation)
            g) Quality assurance
        iv. Research on individual or group characteristics or behavior include but are not limited to the following areas:
            a) Perception
            b) Cognition
            c) Motivation
            d) Identity
            e) Language
            f) Communication
            g) Cultural beliefs or practices
            h) Social behavior

v. The proposal continues research previously approved by IRB under but not limited to any of the following circumstances.

a) The research is permanently closed to the enrollment of new clients

b) Clients have completed research-related interventions

c) The research remains active only for long-term follow-up of participants

d) No participants have been enrolled and no additional risks have been identified

e) The remaining research activities are limited to data analysis

13. Proposals may be exempt from review if the research or demonstration projects are conducted by or subject to the approval of CFSA management and designed to study, evaluate, or examine any of the following topic areas:
    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
    d. Possible changes in methods or levels of payment for benefits or services under those programs

14. If research is not being conducted in accordance with IRB requirements or has been associated with unexpected serious harm to participants, it will be suspended or terminated. Within 10 business days of an IRB decision, IRB notifies the principal investigator in writing of the reasons for suspension or termination of research. Notification must include the investigator's ability to revise and resubmit a new proposal.
    a. If IRB has not received a response within 60 business days of the notification of suspension or termination, the proposal is rejected.
    b. If the proposal is rejected under the stipulation above, it must be resubmitted as a new proposal for consideration by IRB membership.

15. In order to approve or accept research covered by this policy, the IRB membership must determine if the following requirements are satisfied:
    a. Risks to clients are minimized
    b. Risks to clients are reasonable in relationship to anticipated benefits (the importance of the knowledge that may be reasonably expected to result)
    c. Selection of clients is equitable
    d. Assent or informed consent is sought from each client or the client's legally authorized representative
    e. Assent and informed consent is appropriately documented
    f. The research plan has adequate provision for monitoring the data collected
    g. The rights and welfare of the clients are protected

C. Assent

1. Assent is an affirmative agreement by a client less than 18 years of age who has not attained the legal age for consent to participate in research. The client must actively show his or her willingness to participate in research rather than just complying with directions.

2. In addition to the client's assent, permission must be granted by parents or guardians to allow their child to participate in research, unless parental permission is waived.

    a. If parental rights *have not been* terminated, the parents must be consulted and given 10 business days before the child may assent to participate in the research.

    b. If parental rights *have been* terminated, the guardian *ad litem* and special interest attorney (if one is appointed for the child) must be consulted before the child may assent to participate in the research.

3. The IRB must determine that adequate provisions are made for the soliciting the assent of a child, when in the judgment of the IRB the child may be capable of providing assent.

4. In determining whether a child is capable of assenting, the IRB must take into account the age, maturity, and psychological state of the child involved. The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree he or she is capable, what his or her participation in research would involve.

5. If the social worker determines that the child has the maturity to understand the implications of participating in research (based on experience with the child and previous information provided from collateral contacts), the child must be consulted about his or her participation.

    - If the child assents, the child's assent must be documented

6. Where research involves greater than minimal risk permission must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available or when one parent has legal responsibility.

7. Permission from parents or guardians must be documented using the informed consent process.

8. If the research involves an issue which the client can give consent outside the research context, regardless of age, under specific state and local laws (e.g., research on sexually transmitted diseases or pregnancy), then instead of assent and parental permission, the client's informed consent is required.

D. Informed Consent

1. "Informed consent" includes the following basic elements that must be provided to clients who are 18 years of age or older or have attained the legal age for consent to research (or the client's legally authorized representative), and to parents or guardians of children who are less than 18 years of age and parental permission is required:

    a. An explanation of the purposes of the research and the expected duration of the client's participation, including a description of the procedures to be followed, and identification of any procedures that are experimental

    b. A description of any reasonably foreseeable risks or discomforts to the client

    c. A description of any benefits to the client or to others that may reasonably be expected from the research

    d. A disclosure of appropriate alternative procedures or courses of treatment, if there are any that might be advantageous to the client

    e. A statement describing the extent to which confidentiality of records identifying the client will be maintained

    f. For research involving more than minimal risk, an explanation as to whether any compensation might be provided, plus an explanation as to whether any medical

treatments are available if injury occurs and if so, what they consist of and where further information may be obtained

g. An explanation of whom to contact for answers to pertinent questions about the research, the participant's rights, and whom to contact in the event of a research-related injury to the subject

h. A statement that participation is voluntary and that refusal to participate must not involve penalty or loss of benefits to which the client is otherwise entitled

i. A statement that the client may discontinue participation at any time without penalty or loss of benefits to which the client is otherwise entitled

2. As applicable, the following additional elements of informed consent must also be provided to each client (or the client's legally authorized representative):

   a. The approximate number of clients involved in the study

   b. A description of any anticipated circumstances under which participation may be terminated by the researcher without regard to the client's consent

   c. Any consequences that might result from a client's decision to withdraw from the research

   d. Procedures for orderly termination of a client's involvement with the research

   e. A statement that significant new findings developed during the course of the research that may impact the client's willingness to continue participation

3. IRB members may approve a procedure that does not include or which alters some or all of the elements of informed consent set forth above, or members may waive the requirement to obtain informed consent based on the following considerations:

   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 the following topic areas:

      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

      iv. There is a possibility of changes in methods or levels of payment for benefits or services under those programs

   b. The research could not practicably be carried out without the waiver or alteration

4. The written consent form should embody the elements of informed consent as indicated above.

   a. The form should be read to the client or the client's legally-authorized representative.

   b. The researcher must give either the client or the representative adequate opportunity to read the form prior to signing.

5. A short form is acceptable providing the document states that the elements of informed consent have been presented orally to the client or his or her legally-authorized representative.

   a. IRB membership must approve the written summary of what is to be said to the client or the representative.

   b. The client or representative must sign the short form.

c. When this method is used, there must be a witness to the oral presentation.
    i. The witness must sign both the short form and a copy of the summary.
    ii. The person actually obtaining consent must sign a copy of the summary.
    iii. A copy of the summary must be given to the client or the representative, in addition to a copy of the short form.

6. If clients consent, or parents or guardians give permission for their child to participate in research, clients and parents or guardians must sign the informed consent form.

E. Monitoring and Observation

IRB members only approve proposals that include the following monitoring components:

1. The proposal specifies methodologies for recording and maintaining data

2. The proposal includes adequate measures for a timely and thorough review of the research

F. Risk Levels

"Minimal risk" means that the probability and magnitude of harm or anticipated discomfort 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.

IRB members must use the following criteria for risk categories to determine the appropriate level of review:

1. Low-risk (less than minimal risk) research <u>without</u> identifying information
    a. The researcher must not contact the client in person but may request access to client or employee data maintained by the Agency or its contractors
    b. No client-identifying information is involved
    c. The following approval requirements apply:
        i. The protocol assures that adequate provisions are in place to safeguard data
        ii. The research complies with all local and federal regulations, including specifications regarding when the Agency may allow access to "private" or "controlled" records for research purposes

2. Low-risk (less than minimal risk) research <u>with</u> identifying information
    a. The researcher must not contact the participant in person but may request access to client or employee data maintained by the Agency or its contractors.
    b. The researcher may review client data or databases that contain the client's name or other identifying information.
    c. The following approval requirements apply:
        i. The researcher has made adequate provisions for soliciting assent or informed consent of clients, as appropriate, including clients who suffer from mental incapacity
        ii. The protocol assures that adequate provisions are in place to safeguard data
        iii. The research complies with local and federal regulations, including specifications regarding when the Agency may allow access to "private" or "controlled" records for research purposes
        iv. The research is conducted by an outside researcher, including an Agency employee conducting research outside the scope of their employment

v. Less-than-minimal risk research involving a client does not qualify for exemption from review except when the research involves observations of public behavior and the researcher does not participate in the activities being observed

3. Minimal risk research
   a. The research involves *intervention or interaction* with the client.
   b. The researcher anticipates the probability and magnitude of harm or discomfort that will be experienced by clients 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.
   c. This category may also include research that does not require interaction (e.g., materials are collected solely for non-research purposes such as medical treatment or diagnosis).
   d. The following approval requirements apply:
      i. The review may be expedited but must include a prior *review of methodology* and a letter of support from the appropriate IRB representative, even if the research is conducted by an Agency employee or an outside researcher
      ii. The researcher has made adequate provisions for soliciting assent or informed consent of clients, as appropriate, including clients who suffer from mental incapacity

4. Greater than minimal risk but providing some direct benefit to clients
   a. The research involves *intervention* with the clients for treatment or survey purposes and the anticipated harm or discomfort involves a greater-than-minimal risk but the intervention presents the prospect of direct benefit to the client.
   b. IRB members may only approve this category based on the following information:
      i. Risk is justified by the anticipated benefit to the client. That is, proposed interventions or procedures have the potential for direct benefit to the client or the intervention or procedure involves a monitoring procedure that is likely to contribute to the client's well-being.
      ii. Relation of the anticipated benefit to the risk is at least as favorable to the client as that presented by available alternative approaches.
      iii. The review includes a prior *review of methodology* and a letter of support from the appropriate IRB representative, even if the research is conducted by an Agency employee or an outside researcher.
      iv. The researcher has made adequate provisions for soliciting assent or informed consent of clients, as appropriate, including clients who suffer from mental incapacity.

5. Greater-than-minimal risk with no direct benefit to clients but likely to yield generalizable knowledge about the client's disorder or condition
   a. The research includes an *intervention or procedure* that does not hold out the prospect of direct benefit to the client or it includes a *monitoring procedure* that is not likely to contribute to the client's well-being but is likely to yield generalizable knowledge about the client's disorder, condition, or the program is designed to assist or ameliorate the client's disorder or condition.
   b. IRB members may only approve this category based on the following information:
      i. Risk represents a *minor increase* over minimal risk (a slight or small increase in the potential for harm or discomfort beyond the minimal risk level that is allowed for healthy, normal, average client)

ii. Interventions or procedures are reasonably commensurate with those inherent in the research clients' actual or expected medical, dental, psychological, social, or educational situations

iii. Interventions or procedures are likely to yield useful information about the client's disorder or condition, and such information is of vital importance for the understanding or amelioration of the disorder or condition

iv. Interventions or procedures are likely to yield generalizable knowledge about the understanding of the programs designed to ameliorate the disorder or condition

v. General program benefits outweigh the risks to subjects

vi. The researcher has made adequate provisions for soliciting assent or informed consent of clients, as appropriate, including clients who suffer from mental incapacity

vii. The review includes a prior *review of methodology* and a letter of support from the appropriate IRB representative, even if the research is conducted by an Agency employee or an outside researcher

c. Children who are wards may participate in research that is greater than minimal risk that may yield program knowledge if the research is related to their status as wards, or is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of clients involved as subjects are not wards.

- An advocate must be appointed for each ward. One advocate may serve more than one child.

6. If the research is minimal risk or greater, the client's guardian *ad litem* (GAL) must be consulted or give approval. If approval is not given, the client must be excluded from the research.

   a. The GAL must be given a description of the research project and be provided with the anticipated start date for the research, as well as a date by which response is required so that they can express any concerns prior to the start date.

      - After the start date, any questions or concerns that the GAL may have is addressed by the IRB.

   b. The GAL must be given at least 10 business days to review and respond to the research proposal.

   c. The GAL's consent must be in writing.

   d. Contact with the GAL must be documented for each client in FACES.

7. Unless there is evidence that the research will benefit the client or program knowledge, IRB members must not approve a study determined to have a greater-than-minimal risk, regardless of whether the researcher is an Agency employee or an outside researcher.

G. Status Reports

A schedule for submitting reports on the status of the research must be included in the original proposal application. Status reports are submitted to the IRB chairperson and should include but not be limited to the following information (as applicable):

1. Number of required clients
2. A summary of any adverse events that may have occurred
3. Description of any unanticipated problems, e.g., risks to clients or others, withdrawal of clients, complaints about the research

4. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review, especially information about risks associated with the research
5. A copy of the current assent and informed consent documents and any newly proposed assent or consent document

H. Privacy and Confidentiality

IRB members determine whether privacy and confidentiality of research clients are protected by noting the following in the research proposal:

1. Whether the research involves observation or intrusions in situations where clients have an expectation of privacy
2. The provisions made for protecting confidentiality of data through coding, destruction of identifying information, limited access to data, or other means
3. The researcher's disclosures to clients about confidentiality

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Child and Family Services Agency

CFSA IRB Proposal Application

Completion of Sections 1-5 is mandatory for all applications. 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

1.1 **Title of the Project** (title must be the same on all study documents):

1.2 **Principal Investigator** ("scientist or scholar" with primary responsibility for the design and conduct of the research project)

1.3

_____ _____

1.4 **Principal Investigator's affiliated institution:**

1.5 **Point of Contact**:

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**************************************

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SECTION 2 – APPLICATION TYPE

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

If **YES**, complete Sections 3-10. 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.

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

If **YES**, complete Sections 3-5 **AND** Section 11.

END OF SECTION 2

SECTION 3 – RESEARCH INFORMATION

3.1 Provide a concise (less than 300 word) 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
- The approximate number of participants involved in the research

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 concise 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 IRB policy, please indicate the specific exemption here:

END OF SECTION 3

SECTION 4 – INFORMED CONSENT PROCESS

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

☐ A written document that embodies the elements of informed consent, signed by the participant (or legal representative).

☐ A written document, that is not signed (justify with criteria in 45 CFR 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 45 CFR 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 45 CFR 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 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.

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 – CHARACTERISTS 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 decisional 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

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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 physical or psychological harm that is ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of healthy persons.

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

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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 – INTERVIEWS, SURVEY OR GROUP MEETINGS INVOLVING THE RESEARCH PARTICIPANTS

9.1 **Describe the methods that will be used to collect information relevant to section 10.**

9.2 **What is the anticipated duration and number of the sessions to collect this information?**

9.3 **Describe the information that will be collected by interview, survey, or group meetings.**

9.4 **If information will be collected by telephone, explain the consent procedure.**

9.5 **How will the privacy of the participants be protected while collecting information?**

9.6 **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.)

9.7 **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):

9.8 **Describe how any survey records (instruments, recordings, etc.) will be labeled or identified to provide a direct, or indirect link, to the participant.**

9.9 **Are survey instruments and letters of prior announcement of intent to contact attached?** ☐ **YES** ☐ **NO**

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

END OF SECTIONS FOR RESEARCH WITH DIRECT INVOLVEMENT OF HUMAN PARTICIPANTS

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SECTION 10 – 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).

10.1 **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.**

10.2 **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.)

10.3 **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.)

10.4 **What type of data will be used for research?**

10.5 **From how many persons did/will the data originate?**

10.6 **From what source(s) will the data be procured?**

10.7 **How will the investigators gain access to the data?**

10.8 **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

10.9 **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

10.10 **How will the permission of the persons from whom the data originated be obtained to use the data for research purposes?**

10.11 **What measures will be taken to keep the research records confidential?**

10.12 **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?**

10.13 **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):

10.14 **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 10**************************************

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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
☐	Documents are dated to indicate the latest revisions.	
☐	The same project title is on the application, the study protocol and the informed consent documents.	
☐	Name of the Principle Investigator is shown.	
☐	Principle Investigator's signature appears on printed copies (1.2).	
☐	Printed copies of all project-specific consent instruments submitted (3.2, 4.2)*.	
☐	Date of most recent version of consent document is shown.	
☐	Printed copies of survey instruments submitted (3.2, 10.9)*.	
☐	Printed copy of Study Protocol submitted (3.2)*.	
☐	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:	

Investigators' Signatures: (required to assure responsibility for the protection of human participants and adherence to the CFSA IRB requirements) also by signing below the investigator acknowledges receiving and reading the Institutional Review Board Policy and Business Process and agrees to abide by the policy guidelines.

_____ _____
Signature Date

_____ _____
Signature Date

_____ _____
Signature Date

_____ _____
Signature Date

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GOVERNMENT OF THE DISTRICT OF COLUMBIA
Child and Family Services Agency

Institutional Review Board (IRB)
Notification Form

Principal Investigator: _____

Co-Investigators: _____

_____

Title: _____

_____

_____

□ Approved

□ Approved with conditions

_____

□ Disapproved

Comments:

1. Research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to the participant will be suspended or terminated.
2. You are required to immediately report any adverse reactions or complications of the project to the CFSA IRB.
3. There may be no change or addition to the project, or changes of the investigators involved, without prior approval of the CFSA IRB.
4. The attached consent statement has been approved by the CFSA IRB. Please copy this document and use for all participants entered into this study.

The investigator shall have a right to revise and resubmit a new proposal.

_____

Chairperson, Institutional Review Board Date

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