



POLICY STATEMENT

Policy Statement 1201
Policy Area: Research and Evaluation
Effective Date: **NOV 25 2003**
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RESEARCH AND EVALUATION

I. COVERAGE

This Policy Statement establishes procedures for conducting research and evaluation projects involving the Court Services and Offender Supervision Agency ("CSOSA") and/or the Pretrial Services Agency ("PSA"), hereinafter collectively referred to as "the Agency." Agency staff with specific responsibilities under the procedures appended to this Policy Statement include the membership of the Research Review Committee (RRC) (CSOSA Director of Research and Evaluation, PSA Director of Strategic Planning, Analysis and Evaluation, CSOSA Associate Director for Community Supervision Services, PSA Director of Operations, and the General Counsel, or their designees; and other members as designated by the PSA and CSOSA directors, respectively).

II. BACKGROUND

Research and evaluation projects serve a valuable purpose by assessing the effectiveness of CSOSA and PSA efforts to carry out their missions and contribute to the knowledge available in the field of community supervision. The Agency encourages periodic program evaluation and other policy-related research by both employees and non-employees who meet this Policy Statement's qualifications.

III. POLICY

The Department of Health and Human Services' policy on Protection of Human Subjects (45 Code of Federal Regulations [C.F.R.] Part 46) is applicable to research involving CSOSA and/or PSA.

Accordingly, the Agency's Research Review Committee ("RRC") shall review research proposals and monitor research projects with regard to:

- Compliance with federal regulations regarding the protection of human subjects (see 45 C.F.R. Part 46);
- Eligibility for protection regarding confidentiality (see 28 C.F.R. Part 22);

- Compliance with Agency policies; and
- Consistency with Agency priorities and/or interests.

Research refers to the systematic investigation, including development, testing, and evaluation, which is designed to develop or contribute to general knowledge. Specific research projects that must be reviewed by the RRC include:

- Program reviews/evaluations undertaken by non-employees (research originating from outside of the Agency) and, thereby, considered **non-Agency research**;
- All research projects undertaken by employees pursuing independent research (research that may use Agency data, but is conducted on behalf of non-Agency interests such as dissertations, journal articles, *etc.*) and, thereby, considered **non-Agency research**;
- All research projects undertaken by employees and contractors on behalf of the Agency (originating from within the Agency), and thereby considered **Agency research**, whose purpose of investigation is outside of scope of evaluation of performance measures as stated in the Agency's Strategic Plan; and
- All research projects undertaken by employees, contractors or non-employees (both **Agency and non-Agency research**) that include the use of human subjects as defined in 45 C.F.R. Part 46.

Research projects limited to routine statistical tabulations and program reviews/evaluations undertaken by Agency employees for administrative purposes only are not subject to the procedures appended to this Policy Statement.¹

IV. AUTHORITIES, SUPERSEDURES, REFERENCES, AND ATTACHMENTS

A. Authorities

Section 11233 of the National Capital Revitalization and Self-Government Improvement Act of 1997 ("Revitalization Act"), Pub. Law 105-33, 111 Stat. 748, D.C. Official Code § 24-133 (2001 Edition); 45 C.F.R. Part 46.

B. Supersedures

None.

¹ The term "administrative purposes" refers to reports and correspondence for internal use, and for external distribution to the General Accounting Office, Office of Management and Budget, and Congress, *etc.*

C. Procedural References

References: Sensitive Offender File Information Policy (July 10, 2000); Management and Administrative Division Directive 500.2 “Safeguarding Sensitive, Unclassified Information;” PSA Confidentiality Guidelines; 5 U.S.C. §§ 552 (Freedom of Information Act) and 552a (Privacy Act); D.C. Official Code §§ 7-1201.01 et seq. (Mental Health Information Act); D.C. Official Code §§ 7-302 and 7-1605 (2001 Edition) (HIV/AIDS confidentiality); 42 C.F.R. Part 2.

D. Attachments

Appendix A. General Procedures

Appendix B. Researcher Submission Guidelines

Appendix C. Research Review Committee Operating Procedures

Appendix D. Researcher Agreements (Human Subjects Protection, Confidentiality Assurance, Privacy and Data Security Certification Requirements, Intellectual Property Provision, Reporting Progress and Publishing Findings)

**Guidance
Disclaimer**

The contents of this guidance do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

APPENDIX A GENERAL PROCEDURES

A. General Considerations for Research Review

- (1) The project must have an adequate research design and contribute to the advancement of knowledge about assessment of risk, community supervision and corrections.
- (2) The researcher must have academic preparation or experience in the area of study of the proposed research.
- (3) The researcher must assume responsibility for the actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.
- (4) If the researcher is conducting a study of special interest to the Agency, but the study is not a joint project involving the Agency, the researcher may be asked to provide the Agency with a copy of the research data accompanied by detailed documentation of the research findings. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

B. Research Monitoring

- (1) In all research projects, the rights, health, and human dignity of individuals involved must be respected.
- (2) The project must not involve medical experimentation and pharmaceutical testing.
- (3) The project must minimize the risk to subjects.
- (4) When applicable, informed consent of the research subject must be sought and documented.

Note: Informed consent would not be necessary, for example, when Agency employees or non-employees are analyzing only archival information in Agency offender/defendant records that does not reveal the identity of individual subjects. In this case, a plan for ensuring data security must be documented.

- (5) Except as noted in the informed consent statement given to the subject, the researcher must not provide research information which identifies a subject to

any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

- (6) The researcher must adhere to applicable provisions of the Privacy Act of 1974, regulations made pursuant to the Privacy Act, PSA Confidentiality Guidelines, the CSOSA Sensitive Offender File Information Policy, Management and Administration Division Directive 500.2 "Safeguarding Sensitive, Unclassified Information," D.C. Official Code §§ 7-302 and 7-1065 (confidentiality of HIV/AIDS records), D.C. Official Code §§ 7-1201.01 et seq. (confidentiality of mental health information), and 42 C.F.R. Part 2 (confidentiality of drug and alcohol treatment records).
- (7) If the researcher requires access to sensitive information, he/she must be eligible for protection from compulsory proceedings afforded by Department of Justice regulations (see 28 C.F.R. Part 22).
- (8) Any research requiring participation by community supervision officers must be reviewed by the Office of Employee Labor Relations to determine if advance notice to the union is required.
- (9) Any researcher must sign the Researcher Agreements in which the researcher agrees to adhere to the provisions of this Policy Statement.

C. Submission and Processing of Research Proposals

- (1) An applicant shall submit the required materials to an appropriate Agency representative to begin the process for RRC review **at least 60 calendar days prior** to the desired start date for the research project.
- (2) The RRC shall review the research proposal and prepare a statement of recommendations for whether or not to proceed with the proposal **no later than 45 calendar days** from the RRC's receipt of the completed submission package (*i.e.*, containing all of the elements contained in Appendix B (RRC Guidance for Submission)). Any outstanding questions or concerns will be communicated to the researcher in writing and must be addressed and/or resolved before approval can be granted. The CSOSA/PSA directors grant final approval or disapproval of the research proposal.

D. Access to Agency Records

- (1) Employees of the Agency, including contractors, who are conducting authorized research projects as part of their official duties may have access to those records relating to the subject that are necessary to the purpose of the research project without having to obtain the subject's consent.

Note: If the offender/defendant records being sought are specifically protected by statute, e.g., HIV/AIDS records (D.C. Official Code §§ 7-302 and 7-1605); mental health information (D.C. Code §§ 7-1201.01 *et seq.*); or drug and alcohol treatment records (42 C.F.R. Part 2), the Agency employee/contractor must obtain the subject's consent, with the following exceptions. The Agency employee/contractor need not obtain the subject's consent in the following two situations: (1) if the Agency employee's/contractor's research does not require the collection of individually identifying information; or; (2) in the case of substance abuse treatment records only, if the Agency employee's/contractor's research is directly related to the subject's diagnosis, treatment, referral, or quality assurance performed in the context of a treatment program. In both instances, the Agency employee will be responsible for ensuring that the individually identifying information is removed and/or the information is being shared in a manner that renders it unidentifiable at the individual level.

- (2) A researcher that is not an Agency employee is limited in access to information by virtue of the Freedom of Information Act, Privacy Act, PSA Confidentiality Guidelines, the CSOSA Sensitive Offender File Information Policy, Management and Administrative Division Directive 500.2 "Safeguarding Sensitive, Unclassified Information," D.C. Official Code §§ 7-302 and 7-1065 (confidentiality of HIV/AIDS records), D.C. Official Code §§ 7-1201.01 *et seq.* (confidentiality of mental health information), and 42 C.F.R. Part 2 (confidentiality of drug and alcohol treatment records). If the subject gives written consent, the researcher conducting an authorized research project may have access to the same records that are accessible to the subject. However, the subject's consent must conform to the specific statutory requirements pertaining to the particular information that is sought.

Note: Pursuant to a valid Freedom of Information Act request, a researcher that is not an Agency employee or an Agency employee conducting research outside of his or her official duties may receive records in a form not individually identifiable.

E. Informed Consent

- (1) Before commencing a research project requiring participation by staff or offenders/defendants, the researcher shall give each participant a written informed consent statement containing the following information:
 - (1) Identification of the principal researcher(s);
 - (2) Objectives of the research project;
 - (3) Procedures to be followed in the conduct of research;
 - (4) Purpose of each procedure;
 - (5) Anticipated uses of the results of the research;
 - (6) Statement of benefits reasonably to be expected;
 - (7) A declaration concerning discomfort and risk to the subject, including a description of the anticipated discomfort and risk;
 - (8) A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice;
 - (9) A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates an intent to commit criminal conduct or harm himself/herself or someone else;
 - (10) A statement that participation in the research project will have no effect on the offender's/defendant's community supervision status; and
 - (11) An offer to answer questions about the research project.
- (2) All researchers (Agency employees, non-Agency employees, and Agency employees conducting research outside of their official duties) shall include in the informed consent statement: 1) a declaration of the authority under which the research is conducted (*e.g.*, Received approval by the RRC on January 1, 2001); and 2) contact information for subjects to contact researcher if necessary.

In addition to presenting the statement of informed consent to the subject, the researcher shall also obtain the subject's signature on the statement of informed consent prior to initiating the research activity. The researcher must document consent unless documentation is waived by the RRC.

Note: A researcher who is an Agency employee is exempt from the informed consent requirements when the research is authorized as part of the employee's official duties and involves analysis of archived administrative records exclusively and does not require direct (active) offender/defendant participation.

Note: A researcher who is not an Agency employee (or an Agency employee conducting research outside of his or her official duties) also is exempt from informed consent requirements when the research is limited to archival data analysis; however, the researcher must make a valid Freedom of Information Act request prior to the grant of access to Agency information database(s).

F. Monitoring Approved Research Projects

- (1) The RRC shall monitor all research projects for compliance with Agency policies. At a minimum, compliance monitoring activities will be conducted on an annual basis.
- (2) The RRC shall produce a summary report on an annual basis, detailing its review activities and status of current RRC-approved research projects. This report shall be submitted to the Directors of CSOSA and PSA, or their designees.

G. Termination or Suspension of the Research Project

The Director of CSOSA in consultation with the Director of PSA may suspend or terminate a research project if it is believed that the project violates this Policy Statement or that its continuation may prove detrimental to the offender/defendant population, the staff, or the orderly operation of the Agency. If a research project is exclusive to CSOSA or PSA, the respective director independently can suspend or terminate a research project if it is believed that the project violates this Policy Statement or that its continuation may prove detrimental to the offender/defendant population, the staff, or the orderly operation of the Agency.

H. Researcher Responsibilities

All researchers shall sign Researcher Agreements, which stipulate the terms and conditions for conducting research with regard to:

- Human Subjects Protection;
- Confidentiality Assurances;
- Privacy and Data Security Certification;
- Intellectual Property Provision; and
- Reporting Progress and Publishing Findings.

APPENDIX B RESEARCHER SUBMISSION GUIDELINES

A. Terms

Research refers to systematic investigation, including development, testing, and evaluation, which is designed to develop or contribute to general knowledge. Specific research efforts that must be reviewed by the RRC include:

- Program reviews/evaluations undertaken by non-employees (research originating from outside of the Agency) and, thereby, considered **non-Agency research**;
- All research projects undertaken by employees pursuing independent research (research that may use Agency data, but is conducted on behalf of non-Agency interests such as dissertations, journal articles, etc.) and, thereby, considered **non-Agency research**;
- All research projects undertaken by employees and contractors on behalf of the Agency (originating from within the Agency), and thereby considered **Agency research**, whose purpose of investigation is outside of scope of evaluation of performance measures as stated in the Agency's Strategic Plan; and
- All research projects undertaken by employees, contractors or non-employees (both **Agency** and **non-Agency research**) that include the use of human subjects as defined in 45 C.F.R. Part 46.

This does not include routine statistical tabulations and program reviews/evaluations undertaken by Agency employees for administrative purposes¹ only.

B. Requirements for Non-Agency Research and Research Involving Human Subjects

The following information must be provided to the RRC for review of any non-Agency research and any research involving human subjects to be undertaken by employees or non-employees:

- (1) A summary statement containing the following information items in the order in which they are listed below:
 - (a) Name(s) and current affiliation(s) of the researcher(s);
 - (b) Title of the study;
 - (c) Purpose of the project;
 - (d) Location of the project;
 - (e) Duration of the study;

¹ The term "administrative purposes" refers to reports and correspondence for internal agency use, and for external distribution to the General Accounting Office, Office of Management and Budget, and Congress, *etc.*

- (f) Research methods to be employed;
 - (g) Sample type and size required and time frame for sample collection;
 - (h) Agency staff and/or resources needed to support the study and description of the support needs;
 - (i) Indication of risk or discomfort to subjects as a result of participation;
 - (j) Anticipated results; and
 - (k) List of deliverables.
- (2) A detailed statement, which includes the following information items in the order in which they are listed below:
- (a) Review of the related literature;
 - (b) Detailed description of the research method;
 - (c) Significance of anticipated results and their contribution to the advancement of knowledge;
 - (d) Benefits of research and/or participation to CSOSA/PSA;
 - (e) Specific resources required from the Agency;
 - (f) Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur;
 - (g) Description of steps taken to minimize any potential risks or discomforts;
 - (h) Description of physical and/or administrative procedures to be followed to: 1) ensure the security of any individually identifiable data that are being collected for the project; and 2) destroy research records or remove individual identifiers from those records when the research has been completed;
 - (i) Description of any anticipated effects of the research project on Agency programs and operations;
 - (j) Relevant research materials such as vitae, endorsements, descriptions of similar work undertaken, sample informed consent statements, questionnaires, and interview schedules;
 - (k) Statement indicating that copies of all deliverables will be provided to CSOSA/PSA; and
 - (l) Statement that copies of any datasets will be provided to CSOSA/PSA at the conclusion of the project.
- (3) Employee and non-employee researchers (for non-Agency and Agency research involving human subjects) must also provide verification that the proposed research has been approved by an independent Institutional Review Board (IRB), including:

- (a) Copy of application for review to IRB; and
- (b) Copy of certification statement from IRB.

In the case that IRB review is contingent upon RRC approval, the RRC may elect to conduct its review with the provision that final approval and initiation of research will not occur until IRB approval has been verified.

C. Requirements for Agency Research

A summary statement containing the following information items in the order in which they are listed below must be provided for any Agency research (that does not involve human subjects) to be undertaken by employees on behalf of the Agency.

- (1) Name(s) and current Agency and Agency component of the employee(s) conducting the research;
- (2) Title of the study;
- (3) Purpose of the project;
- (4) Location of the project;
- (5) Methods to be employed;
- (6) Anticipated results;
- (7) Duration of the study;
- (8) Sample size required and/or time frame for sample collection;
- (9) Number of Agency staff needed to support the study and description of the support needs;
- (10) Specific resources required from the Agency;
- (11) Description of any anticipated effects of the research project on Agency programs and operations; and
- (12) List of deliverables to the Agency.

Additionally, a statement of approval from the appropriate Agency authority is required.

D. Requirements for Informed Consent

If the proposed research requires participation by staff or offenders/defendants, a copy of the informed consent form to be used must be submitted. The informed consent form must contain the following information:

- (1) Identification of the principal researcher(s);
- (2) Objectives of the research project;
- (3) Procedures to be followed in the conduct of research;
- (4) Purpose of each procedure;
- (5) Anticipated uses of the results of the research;
- (6) Statement of benefits reasonably to be expected;

- (7) A declaration concerning discomfort and risk to the subject, including a description of the anticipated discomfort and risk;
- (8) A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice;
- (9) A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates an intent to commit further criminal conduct or harm himself/herself or someone else;
- (10) A statement that participation in the research project will have no effect on the offender's/defendant's community supervision status; and
- (11) An offer to answer questions about the research project.

A researcher who is not an Agency employee, in addition to presenting the statement of informed consent to the subject, shall also obtain the subject's signature on the statement of informed consent prior to initiating the research activity.

If the researcher is an employee of the Agency, the informed consent statement also must include:

- (1) Declaration of the authority under which the research is conducted (*e.g.*, Received approval by the RRC on January 1, 2001); and
- (2) Contact information for subjects to contact researcher if necessary.

A researcher who is an Agency employee is exempt from the informed consent requirements when the research is authorized as part of the employee's official duties and involves analysis of archived administrative records exclusively and does not require direct (active) offender/defendant participation. A researcher who is not an Agency employee (or an Agency employee conducting research outside of his or her official duties) also is exempt from informed consent requirements when the research is limited to archival data analysis; however, these researchers must make a valid Freedom of Information Act Request prior to the grant of access to Agency information database(s).

E. Other Requirements

An original plus five (5) copies of the complete set of submission materials must be provided.

F. Other Considerations

Once all of the required materials are submitted to the appropriate Agency representative, and the review has been initiated formally, the RRC will review the research proposal and prepare a Recommendation Statement for the Director(s) within 45 business days.

Any outstanding questions or concerns will be communicated to the researcher in writing and must be addressed and/or resolved before approval can be granted. It is advisable to begin the review process 45 to 60 days before research activities must begin.

If the research proposal is supported, the researcher will be required to sign the following agreements:

- Human Subjects Protection
- Confidentiality Assurance
- Privacy and Data Security Certification
- Intellectual Property Provision
- Reporting Progress and Publishing Findings

APPENDIX C
RESEARCH REVIEW COMMITTEE OPERATING PROCEDURES

A. RRC Composition

(1) Membership

The directors of CSOSA and PSA appoint respective agency representatives who serve on the RRC. Minimum composition of the five-member RRC must include each of the following, or their designees:

- CSOSA Director of Research and Evaluation;
- PSA Director of Strategic Planning, Analysis and Evaluation;
- CSOSA Associate Director for Community Supervision Services;
- PSA Director of Operations; and
- Agency General Counsel.

Additional members may be designated by the CSOSA and PSA directors, respectively.

(2) Co-Chairs

One RRC member from CSOSA and one from PSA will chair the RRC jointly. The CSOSA and PSA directors will designate their respective chairs.

(3) RRC Coordinator

A Coordinator who will be selected by the Agency directors will staff the RRC. The Coordinator is responsible for coordinating RRC activities, which include overseeing the administrative tasks associated with processing proposal reviews, producing and routing recommendation statements, monitoring and record-keeping, serving as the liaison to researchers, and developing any necessary policy and/or procedures or other documentation.

The Coordinator is responsible for supervising any assigned support staff in their performance of RRC-related duties.

The Coordinator may establish subcommittees and/or work groups independently or at the request of the RRC to undertake assignments in support of RRC activities.

B. Review Process

(1) Review Initiation

Though a research proposal may become known to the Agency through any number of channels, review begins when the RRC coordinator has received all of the required submission materials (as specified in the Submission Guidance) and formally initiates the review process.

(2) Review Procedures and Time Frames

The RRC review for each submission is expected to be completed within 45 calendar days.

Once RRC members receive the submission materials, each member must submit his/her review comments in writing to the RRC Coordinator.

The Coordinator then will compile the RRC review comments and prepare a draft Recommendation Statement for review by the Committee. Thereafter, the Coordinator will send the final Recommendation Statement to the Agency directors, who are expected to review the statement and indicate acceptance or rejection of the recommendation within two weeks.

(3) RRC Recommendations

Pursuant to its review of the proposed research, the RRC will produce a Recommendation Statement to inform and advise the directors of CSOSA and PSA of their decision to approve or disapprove supporting the proposed research. The recommendation will be one of the following:

- Support the research as proposed;
- Support the research with conditions; or
- Do not support the research as proposed.

The Statement of Recommendation will include detailed comments to substantiate the recommendation, including:

- Statement indicating compliance or non-compliance with federal regulations regarding the protection of human subjects and eligibility or non-eligibility for protection regarding confidentiality with pertinent references to applicable documentation;
- Statement indicating 1) compliance and/or no evidence of non-compliance, or 2) non-compliance with Agency policies with pertinent references to the proposal and/or other materials submitted by researcher;

- Statement indicating consistency or inconsistency with Agency priorities and/or interests with pertinent references to the proposal and/or other materials submitted by researcher;
- Statement indicating any other questions, issues or concerns with sufficient explanation; and
- Statement indicating any specific action to be taken by researcher (*e.g.*, submit additional information, answer specific questions, clarify particular points, *etc.*) to address or resolve any outstanding questions, issues or concerns.

(4) Recommendation Implementation

The procedures for implementing each recommendation are as follows:

- (a) If the RRC's recommendation is to **support the research as proposed**, and the recommendation is accepted by the director(s), the Statement will be sent to the researcher who then may begin implementation of the research project.
- (b) If the recommendation is to **support research with conditions**, the Statement will be sent to the researcher who then must address any outstanding issues as indicated in the Statement. Once these are addressed satisfactorily, the researcher may begin implementation of the research project.
- (c) If the recommendation is **do not support the research as proposed**, a preliminary Statement will be sent to the researcher who will be asked to indicate if he/she intends to revise the proposal to address the stated concerns and resubmit it for review. If the researcher does not intend to resubmit the proposal, the preliminary Statement will be finalized and sent to the directors.

C. Monitoring and Reporting

(1) Monitoring Approved Research Projects

After the initial review of the proposed research, the RRC will monitor all research projects on an ongoing basis for compliance with Agency policies. Compliance monitoring activities may be conducted at any time during the course of the project, and at a minimum of once annually.

(2) Terminating or Suspending Research Projects

If it is believed that a research project violates Agency policy or that its continuation may prove detrimental to the offender/defendant population, the staff, or the orderly operation of the Agency; the RRC must make a recommendation to the CSOSA and PSA directors, who may decide to terminate or suspend the research project.

(3) Record-Keeping

(a) RRC Reporting

The RRC shall produce a summary report on an annual basis, which details its review activities and status of current RRC-approved research projects. This report shall be submitted to the Directors of CSOSA and PSA.

(b) Project Files

The RRC is responsible for maintaining a file on each research project that it has reviewed, and keep each project file for at least three years following receipt of a final report and/or any findings resulting from the research.

The RRC research project file should include:

- Original copies of the researcher's submission materials (summary statement, detailed statement, full proposal submitted to IRB, and IRB review verification);
- Signed researcher agreements;
- Statement of Recommendation;
- Any subsequent researcher or Agency comments or responses to Statement of Recommendation;
- Any correspondence between the researcher and CSOSA/PSA pertaining to the research;
- Progress reporting;
- Original or copies of signed informed consent statements;
- Documentation of status changes (*e.g.*, suspension, termination); and
- Publication of results.

(c) Administrative Files

The RRC is responsible for maintaining administrative files that include:

- Minutes of RRC meetings at which action concerning the research project was taken;
- Any other correspondence or information relevant to any decisions about research projects; and
- Any correspondence pertaining to changes in the RRC membership and policy statement;
- Current copies of RRC documents including the Submission Guidance, Researcher Agreements and other forms; and
- Annual reports of RRC activities.

The minutes of RRC meetings must include:

- Attendance at meetings;
- A record of any actions taken, including votes for, against, and abstaining concerning any research proposal;
- A basis for requiring changes to or disapproving a research project; and
- A summary of any discussion of a significant issue relating to the research project.

APPENDIX D
RESEARCHER AGREEMENTS

Human Subjects Protection

Confidentiality Assurance

Privacy and Data Security Certification Requirements

Intellectual Property Provision

Reporting Progress and Publishing Findings

HUMAN SUBJECTS PROTECTION

Name and Affiliation of Principal Researcher(s)

Title of Research Project Covered Under This Agreement

Note: All references to the “IRB” in this statement refer to the Institutional Review Board that reviewed and approved the abovementioned research.

As the Principal Researcher:

1. I am familiar with the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 C.F.R. Part 46).
2. I understand and accept the responsibility to comply with the standards and requirements stipulated in the above document and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3. I will abide by all determinations of the IRB and will accept the final authority and decisions of the IRB, including, but not limited to, directives to terminate participation in designated research activities.
4. I will report promptly to the IRB and to the CSOSA/PSA primary point of contact for the research project any proposed significant changes in the research conducted under this Agreement.
5. I will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
6. I will report immediately to the IRB and to the CSOSA/PSA primary point of contact for the research project any unanticipated problems in the research project that involve risks to subjects or others.
7. If required, I will seek, document, and maintain records of informed consent from each subject or the subject’s legally authorized representative as required under HHS regulations and stipulated by the IRB; and/or as required by the Agency.
8. I acknowledge and agree to cooperate in the IRB’s responsibility for initial and continuing review, record keeping, reporting, and certification. I will provide all

information requested by the IRB and the CSOSA/PSA Research Review Committee in a timely fashion.

9. I will not enroll subjects in research under this Agreement prior to the review and approval of the project by the IRB and the CSOSA/PSA Research Review Committee.
10. I acknowledge that my primary responsibility is to safeguard the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.
11. I understand that any CSOSA/PSA site may have unique rules and requirements, and I agree to abide by the rules and requirements of the facilities where I conduct my research.
12. I understand that it is my responsibility to ensure that the conduct of researchers (employees, students, and/or contractors) working on this project complies with the conditions outlined under this agreement.

Signature(s):

Principal Researcher Date

Co-Principal Researcher Date

CONFIDENTIALITY ASSURANCE

Name and Affiliation of Principal Researcher(s)

Title of Research Project Covered Under This Agreement

Research project staff has an obligation to research subjects from whom we gather personal information to protect their identities and the information they provide to the researcher. We will conduct any research activities in compliance with the requirements of 28 C.F.R. Part 22; and pursuant to CSOSA Sensitive Offender File Information Policy, Management and Administration Division Directive 500.2; PSA Confidentiality Guidelines; D.C. Official Code §§ 7-1201 et seq. (mental health information); D.C. Official Code §§ 7-302 and 7-1605 (2001 Edition) (HIV/AIDS confidentiality); and 42 C.F.R. Part 2 (confidentiality of drug and alcohol treatment records). The identity of persons interviewed and the related data are to remain confidential and disclosure of identities and related information is strictly forbidden. Contents of interviews are not to be discussed with anyone except project staff, and only as it is necessary to complete the assigned work. Additionally, sensitive interview information should not be discussed anywhere it could be overheard by persons who are not authorized to know this information. Additional special conditions apply to the disclosure of mental health, HIV/AIDS, and drug and alcohol treatment records and information and are included within the provisions below.

As the Principal Researcher:

1. I agree to protect the confidentiality of all information identifiable to a private person that is collected in the conduct of my work for the project.
2. I agree to not disclose or discuss any identifiable information that is learned during the course of my employment as project staff, contractor, or subcontractor anyone, including an employer, other than project staff members who have a need to know this information; nor in any research products.
3. I agree that I have been informed that CSOSA/PSA require that the research is compliant with 28 C.F.R. Part 22 and 45 C.F.R. Part 46, which govern the use and revelation of research and statistical information identifiable to a private person, and that the researcher, as a member of the project staff also must comply with these regulations.

4. I agree not to disclose any information regarding a subject's mental health and HIV/AIDS records without written voluntary consent of that person and to renew consent if the study exceeds the 60-day term of consent validity; notwithstanding exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates an intent to commit further criminal conduct or harm himself/herself or someone else; and/or is deemed by a court to be essential to safeguard the physical health of others.
5. I agree to grant access to any mental health information I have obtained about a subject in the course of the research if the subject requests this.
6. I agree to follow the procedures established by the Privacy and Data Security Certification and to prevent unauthorized access to information identifiable to a private person.
7. I understand that my signing this agreement is a condition of my being able to conduct the research study.
8. I understand that it is my responsibility to ensure that the conduct of researchers (employees, students, and/or contractors) working on this project complies with the conditions outlined under this agreement.

By signing this statement, I acknowledge that I understand the rules and regulations surrounding the protection of confidential information and violation of these provisions is a criminal offense that can result in fines and/or imprisonment, in addition to any other penalty imposed by law. Violation of the provisions governing the confidentiality of mental health records constitutes a misdemeanor with penalties of a fine not more than \$1,000 or imprisonment for not more than 60 days, or both. Anyone who obtains mental health information under false pretenses or through deception is guilty of a misdemeanor and shall be fined not more than \$5,000 or imprisoned not more than 90 days, or both. Violation of provisions governing the confidentiality of drug and alcohol treatment records constitutes a criminal offense with penalties of a fine not more than \$500 for the first offense and not more than \$5,000 for each subsequent offense.

Signatures:

Principal Researcher

Date

Co-Principal Researcher

Date

PRIVACY AND DATA SECURITY CERTIFICATION REQUIREMENTS

The Privacy and Data Security Certification must be prepared by the Principal Researcher(s) in accordance with the provisions outlined below, and approved by the Research Review Committee prior to the commencement of research activities.

In order to ensure confidentiality and data security, all research activities must be conducted in compliance with the requirements of 28 C.F.R. Part 22; and pursuant to CSOSA Sensitive Offender File Information Policy, PSA Confidentiality Guidelines, Management and Administration Division Directive 500.2; D.C. Official Code §§ 7-1201 et seq. (mental health information); D.C. Official Code §§ 7-302 and 7-1605 (2001 Edition) (HIV/AIDS confidentiality); and 42 C.F.R. Part 2 (confidentiality of drug and alcohol treatment records).

As the Principal Researcher, you must provide written documentation of your adherence to privacy requirements and a data security plan. This must include the provisions listed below as well as any additional special conditions that pertain to the research to be undertaken. The Privacy and Data Security Certification must be signed by the Principal Researcher(s) and approved by the Research Review Committee prior to the commencement of research activities.

The Principal Researcher(s) must certify that:

1. Data identifiable to a private person will not be used or revealed, except as authorized in the laws, policies and regulations referenced above.
2. Any private person from whom identifiable information is to be collected or obtained shall be notified, in accordance with laws, policies and regulations referenced above, that such data will be used or revealed only for research or statistical purposes and that compliance with the request for information is not mandatory and participation in the project may be terminated at any time. In addition, the researcher must certify that where findings in a project cannot, by virtue of sample size or uniqueness of subject, be expected to totally conceal the identity of an individual, such individual shall be so advised.
3. Access to the data will be limited to those project staff having a need for such data and that such persons shall be advised of and agree in writing to comply with the laws, policies and regulations referenced above.
4. All staff, contractors, subcontractors, and consultants requiring access to identifiable data will agree, through conditions in their subcontract or consultant agreement, to comply with the requirements of laws, policies and regulations referenced above, regarding information transfer agreements. The researcher also

certifies that CSOSA/PSA will be provided with copies of any and all transfer agreements before they are executed as well as the name and title of the individual(s) with the authority to transfer data.

5. Adequate precautions will be taken to ensure administrative and physical security of identifiable data and to preserve the confidentiality of the personally identifiable information.
6. If applicable, a log will be maintained indicating that 1) identifiable data have been transferred to persons other than employees of CSOSA/PSA and/or researcher staff, contractors, and subcontractors; and 2) such data have been returned or that alternative arrangements have been agreed upon for future maintenance of such data, in accordance with laws, policies and regulations referenced above.
7. Project plans will be designed to preserve the confidentiality of private persons to whom information relates, including where appropriate, name-stripping, coding of data, or other similar procedures.
8. Copies of all questionnaires that have already been designed for use in the project are attached to this Privacy and Data Security Certificate. The researcher also must certify that any questionnaires developed during the project period will be provided to CSOSA/PSA prior to being administered.
9. Project findings and reports prepared for dissemination will not contain information which reasonably can be expected to be identifiable to a private person, except as authorized by the laws, policies and regulations referenced above.
10. All project staff, contractors, subcontractors, and consultants have been advised of and have agreed, in writing, to comply with all procedures to protect privacy and the confidentiality of personally identifiable information.
11. To comply with the requirements in 28 C.F.R. Part 22, and pursuant to D.C. Official Code §§ 7-1201 et seq. (mental health information), D.C. Official Code §§ 7-302 and 7-1605 (2001 Edition) (HIV/AIDS confidentiality, and 42 C.F.R. Part 2 (confidentiality of drug and alcohol treatment records); the following safeguards are incorporated into the project plan and attached to the Privacy and Data Security Certification:
 - (a) Procedures to notify subjects, or, if notification is to be waived, a justification must be provided.

- (b) Procedures developed to preserve the confidentiality of personally identifiable information.
 - (c) Justification for the collection and/or maintenance of any data in identifiable form, if applicable.
 - (d) Procedures to insure the physical and administrative security of data, including, if applicable, a description of those procedures used to secure a name index.
 - (e) Description of any institutional limitations or restrictions on the transfer of data in identifiable form, if applicable.
 - (f) Procedures for data storage.
 - (g) Procedures for the final disposition of data.
 - (h) Name and title of any individual(s) with the authority to transfer data to the Agency or among project staff, contractors, subcontractors, and consultants to whom data access is restricted.
 - (i) Name and title of individual authorized to determine the final disposition of data.
 - (j) Name and title of any project staff, contractors, subcontractors, and consultants to whom data access is restricted.
12. The Agency shall be notified of any material change in any of the information provided in this Privacy and Data Security Certification.
13. It is his/her responsibility to ensure that the conduct of staff, contractors, subcontractors, and consultants working on this project complies with the conditions outlined under this agreement.

INTELLECTUAL PROPERTY PROVISION

Name and Affiliation of Principal Researcher(s)

Title of Research Project Covered Under This Agreement

As the Principal Researcher:

1. I hereby convey to the United States a royalty-free, non-exclusive, irrevocable license to reproduce, publish, translate, and use for any governmental purpose any copyrightable material developed as a result of research conducted under this Agreement.
2. I hereby convey to the United States a royalty-free, non-exclusive, irrevocable license to make and use for any governmental purpose any invention or trade secret developed as a result of research conducted under this Agreement.
3. I hereby agree to forever forebear from asserting against the United States any trademark or service mark rights in the name of any product or service developed as a result of research conducted under this Agreement.
4. I understand that it is my responsibility to ensure that the conduct of researchers (employees, students, and/or contractors) working on this project complies with the conditions outlined under this agreement.

Signature(s):

Principal Researcher

Date

Co-Principal Researcher

Date

REPORTING PROGRESS AND PUBLISHING FINDINGS

Name and Affiliation of Principal Researcher(s)

Title of Research Project Covered Under This Agreement

As the Principal Researcher:

1. For a project lasting more than six (6) months, I will submit a progress report to the RRC at the end of six (6) months from the date of signature and then at least once per year after the submission of the first report.
2. For a project lasting less than six (6) months, I will submit a progress report to the RRC at a point midway between the initiation and termination of the research project.
3. At least 30 business days before any report of findings is to be released to the public, I will provide a copy (including an abstract) to the RRC.
4. In any publication of the research findings, I will acknowledge the Agency's participation in the research project.
5. In any publication of the research findings, I will expressly disclaim approval or endorsement of the published material as an expression of the policies of the Agency.

Signature(s):

Principal Researcher

Date

Co-Principal Researcher

Date