

EMPLOYEE GUIDE TO UNDERSTANDING THE CSOSA/PSA RESEARCH AND EVALUATION POLICY

Research Review Committee
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EMPLOYEE GUIDE TO UNDERSTANDING THE CSOSA/PSA RESEARCH AND EVALUATION POLICY

This guide is designed to help employees understand the CSOSA/PSA (Agency) Research and Evaluation Policy Statement 1201 (Policy) by answering frequently asked questions. The policy outlines two primary directives:

1. Requires that all research and evaluation projects conducted by the Agency or with Agency data be compliant with federal regulations and District of Columbia (District) laws; and
2. Establishes the Research Review Committee (RRC) as the body responsible for reviewing proposed research to ensure that it is compliant with federal regulations, District laws, and Agency policy and is consistent with Agency priorities and/or interests.

1. What are the requirements for research under the Policy?

As a federal agency, CSOSA/PSA must comply with the Department of Health and Human Services' policy on protection of human subjects.¹ Any research supported by the Agency must ensure that:

- Proper measures are taken by the researcher to safeguard the rights and welfare of each research subject; and
- The subject's rights and welfare must take precedence over the goals and requirements of the research.

The Policy requires that research activities be compliant with the standards that ensure the confidentiality of research participants from whom personal information is gathered. Such standards include federal laws and regulations,² District laws³ and Agency policies.⁴ These provisions generally require that:

- The identity of persons interviewed and the related data remain confidential and disclosure of identities and related information is strictly forbidden;

¹ 45 CFR Part 46.

² 5 USC § 552a(b)(5) [Privacy Act- disclosure of records for statistical research], (28 C.F.R. § 20.33 (security addendum required to disclose FBI rap sheets to non-criminal justice parties), 28 CFR Part 22 (Confidentiality of Identifiable Research and Statistical Information), and 42 C.F.R. Part 2 (confidentiality of drug and alcohol treatment records)).

³ D.C. Official Code § 7-1201 et seq. (mental health information), and D.C. Official Code §§ 7-302 and 7-1605 (2001 Edition) (HIV/AIDS and cancer confidentiality, D.C. Official Code §§ 16-2331 and 16-2332 (juvenile case and social records)).

⁴ CSOSA Sensitive Offender File Information Policy, Management and Administration Division Directive 500.2 and PSA Confidentiality Guidelines.

- The contents of interviews not be discussed with anyone except project staff,⁵ and only as it is necessary to complete the assigned work;
- Sensitive interview information not be discussed anywhere it could be overheard by persons who are not authorized to know this information;
- Special conditions apply to the disclosure of mental health, HIV/AIDS and cancer, juvenile records, and drug and alcohol treatment records and information.

The Policy also requires that researchers adhere to privacy requirements and data security plans in accordance with federal regulations, District laws and Agency policies. These provisions generally require that:

- No identifiable information about a person be used or revealed in any way;
- Any identifiable data that is obtained about a person be used only for research-related purposes;
- Any person from whom identifiable information is to be collected be notified, the purpose of the research study be explained to him/her, and a written consent be obtained;
- Only authorized project staff be allowed access to the data; and
- Adequate precautions be taken to ensure the security of data.

2. How do I know if a project is considered research?

A project is considered to be "research" if it fits within the Agency's definition/description. The Agency defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"⁶ in a field. This could involve examination of existing data files, collection of new data, review of document files, and/or interviews.

Research does not include routine statistical tabulations and program reviews/evaluations undertaken by Agency employees for administrative purposes⁷ only.

3. How do I know if a research project requires RRC review?

All non-Agency research and research involving the use of human subjects requires RRC review.

Non-agency research includes:

- Research that originates from outside the Agency;
- Research undertaken by non-employees; and

⁵ Project staff includes anyone working on the research project.

⁶ 45 C.F.R. § 46.102.

⁷ 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.*

- Research undertaken by employees pursuing independent studies using Agency data and/or information.

Research originating from within the Agency is considered Agency research. Agency research requires RRC review only when the purpose of investigation is outside of scope of evaluation of performance measures as stated in the Agency's Strategic Plan.

All research involving the use of human subjects – both Agency and non-Agency – requires RRC review. A human subject is defined simply as an individual who is or becomes a participant in research, either as a recipient of the test activity or as a control.

4. What are the role and responsibilities of the RRC?

The RRC conducts reviews for the purpose of making recommendations to inform and advise the directors of CSOSA and PSA in their decisions to approve or disapprove support of the proposed research projects. Each recommendation must provide detailed comments to substantiate the recommendation, including statements indicating the following:

- Compliance or non-compliance with protection of human subjects regulations and eligibility or non-eligibility for protection regarding confidentiality;
- Compliance and/or no evidence of non-compliance or specific evidence of non-compliance with Agency policies;
- Consistency or inconsistency with Agency priorities and/or interests;
- Questions, issues or concerns with sufficient explanation; and
- Specific action to be taken by researcher to address or resolve any outstanding questions, issues or concerns.

The RRC makes a recommendation to the Agency's Director(s) to support the research as proposed, to support the research with conditions, or to not support the research as proposed. The Director(s) considers this recommendation when making the final determination to approve or disapprove the proposed research.

RRC membership and operating procedures are provided as Appendix C of the Policy.

Review by the RRC does not substitute review by an institutional review board (IRB).

5. What is an institutional review board?

Until 1991, federal agencies and departments that conduct research used various policies and procedures to protect human subjects. To eliminate confusion, the departments and agencies adopted a common federal policy, known as The Common Rule for the protection of human research subjects. The Common Rule is the federal policy (contained in the Code of Federal Regulations, Title 45, Part 46) adopted by 16 federal agencies as regulation and is based on the ethical principles of using human subjects in research. The three basic principles of The Common Rule are respect for persons, beneficence and justice. The application of these

principles is achieved through the assurance of informed consent, minimized risk, and the fair selection of subjects.

The Common Rule requires that agencies conducting research establish an IRB which takes the responsibility for assuring the federal government that it will provide and enforce protections for human subjects in research conducted by the institution.

6. What is the difference between the RRC and an IRB?

An institutional review board (IRB) is an independent administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities. Its function and authority are specified by federal regulations⁸ and any federally-supported research involving human subjects must have approval from an IRB as outlined by the Federal Office of Human Subjects Protection.⁹

The Agency's policy statement for research and evaluation¹⁰ creates the RRC to conduct reviews for the purpose of making recommendations to the Director(s) to support or not support proposed research projects. The RRC is not an independent organization, but rather an internal review body. Its membership is comprised of Agency staff that are selected at the discretion of the Director(s) to represent research, operations and legal interests. The RRC is similar in structure to an IRB; however, since it is an internal entity, it is not sanctioned to approve research projects that involve human subjects. Also, the RRC does not have independent authority from the Director(s). It does not approve research, but makes a recommendation of support or non-support to the Director(s). The Director(s) have the authority to approve or disapprove the research.

While the RRC would review the protocol to determine whether the Agency should support the proposed research, the IRB would make an independent determination whether to approve or disapprove the protocol based upon whether or not the human subjects are adequately protected.

Research that has been reviewed and approved by an IRB may be subject to review and disapproval by the RRC and/or the Director(s) of the Agency. However, the RRC and/or the Director(s) may not approve research if it has been disapproved by the IRB.

7. What is the difference between research and a FOIA request?

The Freedom of Information Act (FOIA)¹¹ enables the public to have access to information regarding the federal government. Public access, however, is regulated by the Privacy Act (PA),¹² which limits the access to information concerning individuals contained in government files.

⁸ 45 C.F.R. § 46.108, and 45 C.F.R. § 46.109.

⁹ 45 C.F.R. § 46.103.

¹⁰ CSOSA/PSA Policy Statement 1201, Research and Evaluation.

¹¹ 5 USC § 552.

¹² 5 USC § 552a.

Often, a researcher's request for data can be handled by the Agency's Office of the General Counsel's (OGC) FOIA Officer if it involves public information that is obtainable from the Agency's system of records. If this is the case, the researcher can make the request directly to the FOIA Officer and does not need to submit a proposal to the RRC.

However, researchers typically desire information more detailed than what is allowable for release through FOIA (*i.e.*, limited by the PA). In this case, he/she must prepare for review by the RRC a detailed research plan that outlines the purpose of the study and the protections that will be taken to ensure privacy, confidentiality, and the protection of human subjects.

8. What should I tell someone who calls to request data or information for a research project?

If you get a call from the public requesting any Agency data or information, ask him/her to call either the FOIA Officer (Renee Barley at 220-5362) or the RRC Co-Chair (Claire Fay) at 220-5553).

9. If I am a student and want to use Agency data or information, what are the requirements?

An employee who wants to use Agency data or information for his/her academic research must submit a proposal to the RRC for review. Even if your supervisor has indicated support for the project, it still must be reviewed by the RRC. The guidelines for submitting a proposal are provided in Appendix B of the Policy.

There basically are two options for an employee researcher to consider:

Option A: The student's study is proposed as non-Agency research, whereby his/her Agency affiliation is not considered as a factor and the proposed research is reviewed with the same criteria established for a researcher not employed by the Agency. The researcher must provide the information required in Appendix B, Section B of the Policy, including a detailed research plan, verification of IRB approval, and protection from compulsory disclosure.

Option B: The student's study is proposed as Agency research, whereby the study is designed in collaboration with an Agency need or interest, can be undertaken within the parameters of his/her Agency position, and the product of the research is usable by the Agency. The researcher must adhere to the requirements of Appendix B, Section C of the Policy. This Section generally requires that a study plan be developed in collaboration with Agency research staff, and that the student acquire approval to use Agency resources from the appropriate Office or Division Director. The study proposal must be reviewed by the RRC before work on the study is started.

If you are working on your Master's thesis or Doctoral dissertation, which may require use of human subjects or special data, either of these options would be appropriate to consider. If you are working on an assignment for a particular class and have a limited timeframe, it might be advisable to modify your study to use only data and information that are publicly available (*e.g.*, strategic plans, performance plans, budget requests, testimony, *etc.*).

10. If I am a supervisor and one of my staff asks for permission to use Agency data or information for academic research, what are my responsibilities?

Supervisors do not have the authority to grant permission to staff for the use of any data and/or information for purposes not associated with their routine duties. Additionally, supervisors do not have the authority to decide whether or not a proposed research project needs to be reviewed by the RRC. Supervisors should inform any staff requesting permission to use Agency data or information for academic research that he/she must prepare a proposal for review by the RRC. The guidelines for submitting a proposal are provided in Appendix B of the Policy.

11. What does the RRC review process entail?

The guidelines for submitting a research proposal for RRC review are provided as Appendix B of the Policy. There are separate guidelines for Agency and non-Agency research, and research involving human subjects.

The required proposal materials should be submitted to the RRC at least 60 calendar days prior to the desired start date for the research project. Before making your submission, it is strongly recommended that you discuss the project with the RRC Coordinator (Claire Fay at 220-5553) to identify any areas of question, concern or clarification that could be addressed to enable a more expeditious review.

In the course of RRC review, questions may arise that need to be addressed by the researcher and might affect the timeframe for completing the review. Once the review is completed, a recommendation statement is prepared for the CSOSA and/or PSA Director(s) to support, not support, or support with conditions. If the Director(s) accepts the RRC recommendation, the RRC informs the researcher.

12. What other Agency policies apply to employees who want to do academic research?

If you are an employee who wants to conduct non-Agency research for academic or other purposes, you must submit a request for approval in accordance with the Agency's Standards of Employee Conduct Directive. The request for approval of a non-Agency research project is a separate process from the RRC review and must be completed prior to beginning the research.

13. What is the purpose of the researcher agreements?

There are five researcher agreements that must be signed by the principal researcher¹³ before the proposed research can begin. They are designed to inform the researchers of their responsibilities with regard to conducting the research, and to provide documentation to the Agency of the researchers' acceptance of these responsibilities. Project staff who work under the supervision of the principal researcher are not required to sign the researcher agreements. The principal researcher accepts responsibility for ensuring that project staff are compliant with the conditions set forth in the agreements. The researcher agreements are provided as Appendix D of the Policy.

a) Human Subjects Protection

The Human Subjects Protection Agreement acknowledges, among other things, that 1) the research has been approved by an IRB, 2) the researcher agrees to uphold the standards and requirements set forth under the IRB approval, and 3) any significant communications that would be sent to the IRB also must be sent to the RRC. The Agreement also states that the researcher is responsible for ensuring that any of his/her project staff also are compliant with the conditions outlined in the Agreement.

b) Confidentiality Assurance

The Confidentiality Assurance Agreement is tailored specifically for use by Agency. Although it is common for researchers to use the confidentiality assurance form provided the Department of Justice's National Institute of Justice (NIJ), this form covers only federal regulations. The Agency's tailored Agreement is expanded to include requirements set forth in federal regulations, District laws and Agency policy. It also states that the researcher is responsible for ensuring that any of his/her project staff also are compliant with the conditions outlined under this Agreement. Therefore, even if researchers provide NIJ's confidentiality assurance form, they still are required to sign the Agency's Agreement.

c) Privacy and Data Security Certification Requirements

As with the Confidentiality Assurance Agreement, the Agency has tailored its Privacy and Data Security Certification. NIJ also provides a privacy certification that researchers commonly include in their proposals. The Agency's tailored Certification requires the researcher to develop a privacy and data security plan specifically for the proposed study (as opposed to signing a template agreement) that must include the provisions listed in the Certification, as well as any additional special conditions that pertain to the research to be undertaken. The Certification also must state that the researcher is responsible for ensuring that any of his/her project staff are compliant with the conditions outlined in the Certification. The Certification must be signed by the Principal Researcher(s) and approved by the RRC before research can begin.

¹³ Principal researcher refers to the individual who is identified by the Agency or external entity to lead the research project.

d) Intellectual Property Provision

The Intellectual Property Provision Agreement sets forth that the Agency has the right to reproduce any material developed as a result of the research; the researcher cannot assume any rights, in exclusion of the U.S. Government, to any material developed as a result of the research; and the researcher is responsible for ensuring that any of his/her project staff also are compliant with the conditions outlined in the Agreement.

e) Reporting Progress and Publishing Findings

The Reporting Progress and Publishing Findings Agreement basically outlines the requirements for progress reporting, Agency acknowledgements and disclaimers in publications, and submission to the Agency of final reports in advance of publication.

14. What happens if I ignore the requirements of this Policy?

Criminal penalties are possible for violations of federal regulations associated with the Agency's CSOSA/PSA Research and Evaluation Policy.¹⁴ Further Agency disciplinary action also may result.

For any additional questions, please contact Claire Fay at 220-5553 or claire.fay@psa.gov.

¹⁴ 42 C.F.R. § 2.4.