DISTRICT OF COLUMBIA
DEPARTMENT OF CORRECTIONS

Program Statement

OPI:	**DIRECTOR**
Number:	**1311.1E**
Supersedes:	**1311.1D (12/15/03)**
Date:	**February 29, 2008**
Subject:	**Research**
Activity	

1. **PURPOSE AND SCOPE.** To establish guidelines for conducting research within the DC Department of Corrections (DOC).

2. **POLICY**

   a. It is the policy of the Department of Corrections (DOC) to engage in aggregate data collection, research and demonstration projects and evaluation and technical assistance to carry out its mission, improve programs, services and operations; and contribute to the knowledge available in the field of Corrections.

   b. DOC prohibits use of inmates for medical, pharmaceutical or cosmetic experiments.

   c. All research shall comply with ethical, legal and regulatory standards.

   d. Routine statistical tabulations and program reviews undertaken by DOC employees for administrative purposes only are not defined as research projects. Research that DOC requests to accomplish its mission and goals and which a DOC employee, contractor or consultant conducts are not defined as research projects.

   e. All research shall be reviewed to ensure that proper safeguards are maintained.

3. **RESTRICTIONS.** DOC, contract employees and non-employees shall not use data that is created or maintained by DOC or conduct any form of research that DOC has not authorized in advance, nor shall any person use DOC data or conduct research contrary to the stipulations in this directive.

4. **APPLICABILITY.** This directive applies to non-employees and external researchers who participate in, conduct or evaluate approved research activities; DOC employees (to include contractor employees and volunteers) who conduct and/or manage approved research activities; and inmates who may be the subject of research activity.

5. **NOTICE OF NON-DISCRIMINATION**

   a. In accordance with the DC Human Rights Act of 1977, as amended, DC Official Code section 2-1401.01 *et seq.*, (Act) the District of Columbia does not discriminate on the basis of actual or perceived: race, color, religion, national origin, sex, age, marital status, personal appearance, sexual orientation, familial status, family responsibilities, matriculation, political affiliation, disability, source of income, or place of residence or business. Sexual harassment is a form of sex discrimination which is also prohibited by the Act. In addition, harassment based on any of the above protected categories is prohibited by the Act. Discrimination in violation of the Act will not be tolerated. Violators will be subject to disciplinary action.

   b. Inmates with disabilities, including temporary disabilities, are housed in a manner that provides for their safety and security. Housing used by inmates with disabilities, including temporary disabilities, is designed for their use and provides for integration with other inmates. Programs and service areas are accessible to inmates with disabilities who reside in the facility. Discrimination on the basis of disability is prohibited in the provision of services, programs and activities.

6. **PROGRAM OBJECTIVES.** The expected results of this program are:

   a. Researchers shall be informed about policy and procedures relating to their research, especially those regarding confidentiality of information.

   b. The research design and the requirements made of staff and/or the researcher or consultant shall be fully understood and agreed upon before any research project proceeds.

   c. Any research conducted shall be properly authorized and monitored so that the interests of the research subjects, the researchers and DOC are safeguarded.

   d. The researcher shall make the research available to DOC for review and comment and provide DOC with a copy of the final report.

   e. The results of the research, when appropriate, shall be used to develop agency goals and objectives and/or improve DOC programs and operations.

7. DIRECTIVES AFFECTED

a. Directive Rescinded

PS 1311.1D (12/15/03)	Management Control-Research Activities

b. Directives Referenced

1)	PS 1300.1	DC Freedom of Information Act (FOIA)
2)	PS 1300.2	Consent to Release Information
3)	PM 1300.3	Health Information Privacy
4)	PS 6000.1	Medical Management

8. AUTHORITY

a. DC Code §22-4201. Technical assistance and research.

b. DC Code §24-211.02 Powers; Promulgation of Rules.

c. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) DC Privacy Rules.

d. Title 7 Human Health Care and Safety, Chapter 12 Mental Health Information, §7-1201.3 and §7-1202.06.

9. STANDARDS REFERENCED

a. American Correctional Association (ACA) 2nd Edition Standards for Administration of Correctional Agencies: 2-CO-1F-09, 2-CO-1F-10, 2-CO-1F-11, 2-CO-1F-12, 2-CO-1F-13, 2-CO-1F-14 and 2-CO-1F-15.

b. American Correctional Association (ACA) 3rd Edition Standards for Adult Local Detention Facilities: 4-ALDF-4D-18, 4-ALDF-7C-02,

10. REQUIREMENTS FOR RESEARCH PROJECTS

a. The research project shall not involve medical experimentation and pharmaceutical testing.

b. The research project shall have an adequate research design and contribute to the advance of knowledge about corrections.

c. The research design must be compatible with both the operation of detention and correctional facilities and the protection of human subjects.

d. Planned methodological changes in a research project shall be submitted for approval.

e. The rights, health and human dignity of individuals involved shall be respected.

f. The project must minimize the risk to subjects, the risks to subjects must be reasonable in relation to anticipated benefits and the probability and magnitude of harm or discomfort anticipated in the research are not greater in themselves that those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

g. The selection of subjects within the institution shall be equitable.

h. When applicable, informed consent shall be sought and documented.

i. The use and disclosure of research data shall comply with applicable federal and local privacy laws with regard to any information.

j. Incentives may not be offered to help persuade inmate subjects to participate.

k. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to individuals who are no longer confined in DOC custody and who are participating in authorized research being conducted by DOC employees or contractors (for example, if study of recidivism).

11. **INTERNAL REVIEW BOARD**

a. An Internal Review Board will be established to review all research proposals prior to their implementation. The DOC Director will designate a group of peers who can objectively assess the research request as members of the IRB. The IRB will scrutinize the research requests and ensure that they do not interfere with department programs and anticipate that the results to be of positive public or department benefit. The primary function of the IRB is to assist researchers in the protection of the rights and welfare of human participants. The IRB will review the research projects for:

a) Compliance with this directive,

b) Its impact on and relevance to inmates and to the correctional process,

c) Its potential impact on legal, security practices and operations, privacy, data quality, cost issues as well as the impact upon DOC employee time and attention that would be associated with the external data request, and

d) Its impact on DOC resources when the research proposal involves significant data.

e) Fairness

f) Identification and minimization of risk

g) Confidentiality

h) Ethical considerations

i) The methodology to be used

b. Upon review of the research request the IRB will forward a written recommendation to the Director for review and final approval.

c. Accountability and progress of the research project will be tracked by the IRB. The IRB will monitor all research conducted within the department and will convene periodically to ensure the integrity of the research request and compliance with this directive is maintained.

Prior to implementing any major changes in the methodology, the researchers must submit these changes in writing to the IRB and wait approval.

12. REQUIREMENTS FOR RESEARCHERS

a. The researcher must have academic preparation or experience in the area of study of the proposed research.

b. The researcher shall assume responsibility and liability to include indemnification and representation for actions of any person engaged to participate in the research project as an associate, assistant or subcontractor to the researcher.

c. The researcher shall adhere to all applicable federal and local privacy laws. Excepted as noted in the informed consent notice and protected health information privacy rules, the researcher shall not provide research information that identifies a subject to any person without the subject’s prior written consent to release the information.

d. 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 pertains or as otherwise restricted under health privacy rules.

e. Any researcher who is not an employee shall sign an agreement that all research activity shall be consistent with the safety, security and order of the institution.

13. **RESPONSIBILITIES**

a. **Director**

1) The Director for DOC has final authority to:

a) Approve or disapprove all research projects,

b) Review and provide comments and clarity on collected data and findings, and

c) Approve or disapprove any disclosure and/or dissemination of information and data.

2) The Director has the authority to plan a research project to study, evaluate or otherwise examine public benefit or service programs, study procedures for obtaining benefits of services under those programs, study possible changes in or alternatives to those programs or procedures, and study possible changes in methods, levels of payment for benefits or services under those programs.

b. **Office of Management Information Technology Services (OMITS).** Under the general direction of the Deputy Director, OMITS shall ensure that agency data is managed and disseminated in accordance with this and other DOC directives.

c. **DOC Privacy Officer.** Under the auspices of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the DOC Privacy Officer shall authorize the use and/or disclosure of any Protected Health Information (PHI) prior to research taking place in the DOC or DOC contract facility.

d. **Wardens.** The Wardens, Central Detention Facility (CDF) and Correctional Treatment Facility (CTF), shall ensure that, when appropriate, correctional supervision is provided to enforce this directive while research is being conducted.

e. **Managers, Supervisors and Employees.** Full cooperation with external research authorities is required and expected. Questions concerning the disclosure of specific documents or information shall be referred to the senior level manager who may also consult with the Office of Internal Controls, Compliance and Accreditation (OICCA).

f. **Employees as Subjects.** Employee participation as subjects shall be in accordance with any existing provisions or collective bargaining agreement dealing with the administration of tests and questionnaires to employees.

1) Full cooperation with external research authorities is required and expected;

2) Any questions concerning the disclosure of private information shall be referred to the DOC Privacy Officer; otherwise

3) Any questions concerning the disclosure of specific documents or information shall be referred to the senior level manager who shall consult with the Office of Internal Controls, Compliance and Accreditation.

14. **RESEARCH REQUESTS**

a. **DOC Employees.** Research applicants who are DOC and contract employees and volunteers providing services on behalf of DC shall initiate the review process at their site of employment and obtain the affected Warden, Administrator or Office Chief's recommendation before forwarding the proposal package to the Director.

b. **Non-Employees**

1) All outside research proposals/requests shall be submitted for approval to the D.C. Department of Corrections, Office of the Director.

2) When submitting a research proposal, the applicant shall complete, in its entirety, the *Request to Conduct Research at the DC Department of Corrections* (Attachment A).

3) When protected health information about the subjects is part of the data set for the research project, the researcher shall also submit DOC-HIPAA Form 12 *Research Access Request.*

4) When there is proper representation from a researcher that the protected health information is needed for the research, PHI shall be used and disclosed only as specifically needed to prepare the research protocol or for a similar preparatory purpose, and no protected health information shall be removed from the premises during the review.

The researcher shall be provided with a copy of the PM 1300.3 Health Information Privacy.

15. **RESEARCH PROPOSAL.** At a minimum the proposal shall include

    1) The name of the research protocol or activity;

    2) The title of the proposed study;

    3) A plain language description of the research protocol or activity, including its purpose and criteria for selecting particular records;

    4) A brief description of the type of protected health information to be disclosed;

    5) A summary of the goals to the study and the justification for the research;

    6) The name, address, and telephone number of the research sponsor and the researcher to whom the disclosures will be made;

    7) An endorsement by a recognized research entity certifying that the proposed project is for valid, scientific, educational, or other public purpose;

    8) A detailed summary of the methodology that will be employed. The methods needs to provide an exact description of all procedures and materials, as well as the activities required of the participant;

    9) A statement that the individual's protected health information may or may not be disclosed for a particular research protocol or other research activity; and

    10) Assistance in contacting the research sponsor and the researcher, if it is reasonably likely that the individual's protected health information will be disclosed for the research protocol or activity.

    11) Estimated date that the research study will end.

16. **DOC MONITORING.** The designated DOC manager shall monitor research projects for compliance with DOC policies.

    a. At a minimum, yearly reviews shall be conducted for those projects that are approved for extended periods, i.e. eighteen (18) months or longer.

    b. After a project begins, staff shall refer matters of concern to OICCA staff. PHI data concerns may be directly referred to the DOC Privacy Officer.

c. Staff coordinating the research project shall report any violations of research policy.

d. In conjunction with the General Counsel, Deputy Director and affected Office Chief/Administrator where the research is conducted, a review and comment on research will be required, if material errors or non-compliance with this Program Statement is discovered prior to the researcher's publication of the project results.

17. **TERMINATION OR SUSPENSION.** The Director, DOC, shall suspend or terminate a research project if it is believed that the project violates research policy or that its continuation may prove detrimental to the inmate population, the staff, or the orderly operation of the facility.

18. **ACCESS TO DOC DATA AND RECORDS**

a. Employees, including consultants, of the DOC who are conducting authorized research projects with the express written approval of the Director or the Director's designee shall have access to those records relating to the subject, which are necessary to the purpose of the research project without having to obtain the subject's consent.

b. A non-employee of the DOC is limited in access to information available under the Freedom of Information Act accept as provided in Sections c and d below.

c. If the subject gives written consent, a non-employee conducting an authorized research project shall have access to the same records that are accessible to the subject.

d. A non-employee of the DOC may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.

19. **INFORMED CONSENT**

a. Before commencing a research project requiring participation by staff or inmates, the researcher shall give each participant a written informed consent statement containing the following information:

1) Identification of the principal investigator(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) A statement of benefits reasonably to be expected.

7) A declaration concerning discomfort and risk, including a description of 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 (the inmate shall be returned to regular assignment or activity by staff as soon as practicable).

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 shall not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself/herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.

10) A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility;

11) An offer to answer questions about the research project.

12) Appropriate additional information as needed to describe adequately the nature and risks of the research.

13) The estimated date of completion of the research project.

b. A researcher who is an employee of the DOC shall include in the informed consent statement a declaration of the authority under which the research is conducted.

c. A researcher who is an employee of the DOC, 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, when:

1) The subject's activity requires something other than response to a questionnaire or interview, or

2) It is determined that the research project or data-collection instrument is of a sensitive nature.

d. A researcher who is employed by DOC (to include contract employees) and is conducting research for official DOC purposes is exempt from informed

consent requirements when the research involves non Protected Health Information archival data analysis exclusively and does not require direct (active) inmate participation.

e. A researcher who is a not an employee of DOC, 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 on material that is not PHI. The researcher shall not be required to obtain the signature if the researcher can demonstrate that the only link to the subject's identity is the signed statement of informed consent, the material is not PHI or that there is significantly more risk to the subject if the statement is signed.

f. The original signed statement of informed consent shall be placed in the specific research project's file at the facility where the research is conducted.

g. A copy of the signed consent form that grants a researcher access to an Inmate’s Central File shall be placed in the non-disclosable portion of the Inmate's File and a copy shall be offered to the inmate.

20. **RESEARCH PROGRESS/STATUS REPORTS.** The researcher shall prepare reports of progress on the research and at least one report of findings. The report of finding shall be affected by the following conditions:

a. At least once a year or more often as the Director shall require, the researcher shall provide the IRB with a report on the progress of the research;

b. The researcher shall distribute one copy of the report to each of the following at least fifteen (15) working days before any report of findings is to be released:

1) Director

2) Deputy Director

3) Internal Review Board, and

4) Administrator who provided data or assistance.

c. The researcher shall include an abstract in the report of findings; and

d. DOC managers shall take relevant research findings into consideration in assessing their programs.

21. PUBLICATION OF RESULTS OF RESEARCH PROJECT

a. A researcher may publish in book form and professional journals the results of any research project conducted under this rule as follows:

   1) The Director approves the publication;

   2) In any publication of results, the researcher shall acknowledge the DOC's participation in the research project; and

   3) The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the DOC.

b. Prior to submitting for publication the results of a research project conducted under this rule, the researcher shall provide two copies of the material, for informational purposes only, to the OICCA Manager.

22. COPYRIGHT PROVISIONS

a. An employee (DOC or contract staff) may not copyright any work prepared as part of his/her official duties.

b. As a precondition to conduct research under this rule, a non-employee shall grant in writing to the DOC a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, translate, and otherwise use or authorize others to publish and use original materials developed as a result of research conducted under this directive.

c. Subject to a royalty-free, non-exclusive, and irrevocable license, which the DOC reserves, to reproduce, publish, translate, and otherwise use and authorize others to publish and use such materials, a non-employee may copyright original materials developed as a result of research conducted under this rule.

23. RECORD-KEEPING

a. DOC shall maintain a file on each research project covered by these regulations in accordance with PS 2000.2, Retention and Disposal of DOC Records.

b. The DOC Privacy Officer shall maintain a record of PHI use and disclosure for research purposes in accordance withy PM 1300.3 Health Privacy Information.

Devon Brown
Director

ATTACHMENTS

Attachment A – Request to Conduct Research at the DOC
Attachment B – Inmate Consent Form – Research Activity