U.S. Department of Justice
Federal Bureau of Prisons

Program Statement

OPI: IPD
NUMBER: 1070.07
DATE: 5/12/99
SUBJECT: Research

1. **[PURPOSE AND SCOPE §512.10. General provisions for the protection of human subjects during the conduct of research are contained in 28 CFR part 46. The provisions of this subpart B specify additional requirements for prospective researchers (both employees and non-employees) to obtain approval to conduct research within the Bureau of Prisons (Bureau) and responsibilities of Bureau staff in processing proposals and monitoring research projects. Although some research may be exempt from 28 CFR part 46 under § 46.101(b)(5), as determined by the Office of Research and Evaluation (ORE) of the Bureau, no research is exempt from 28 CFR part 512. For the purpose of this rule, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.]**

Research projects serve a valuable purpose by assessing the effectiveness of Bureau efforts to carry out its mission and contribute to the knowledge available in the field of corrections. The Bureau encourages periodic program evaluation and other policy-related research by both employees and non-employees who meet this Program Statement's qualifications.

Generally, research which Bureau managers request to accomplish the Bureau's mission and goals and which a Bureau employee or contractor conducts is exempt from the regulations in 28 CFR part 46 under § 46.101(b)(5).

2. **SUMMARY OF CHANGES.** The Bureau of Prisons Directives affected and the American Correctional Association Standards referenced in this Program Statement have been updated.

[Bracketed Bold - Rules]
Regular Type - Implementing Information

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

a. The knowledge available about inmates and correctional programs will be increased.

b. Any research conducted in the Bureau will be properly authorized and monitored so that the interests of the research subjects, the researchers, and the Bureau are adequately safeguarded.

c. Reports of research findings will be provided to the Bureau.

4. **DIRECTIVES AFFECTED**

a. **Directive Rescinded**

PS 1070.05 Research (2/12/97)

b. **Directives Referenced**

PS 1237.11 Information Security Programs (10/24/97)
PS 1351.04 Release of Information (12/5/96)
PS 6000.05 Health Services Manual (10/31/97)

Master Agreement between the Federal Bureau of Prisons and Council of Prison Locals (American Federation of Government Employees)

c. Rules cited in this Program Statement are contained in 28 CFR 512.10-21.

5. **STANDARDS REFERENCED**

a. American Correctional Association 3rd Edition Standards for Adult Correctional Institutions: 3-4105, 3-4106, 3-4107,3-4108, 3-4109, 3-4110, 3-4373

b. American Correctional Association 3rd Edition Standards for Adult Local Detention Facilities: 3-ALDF-1F-09, 3-ALDF-1F-10, 3-ALDF-1F-11, 3-ALDF-4E-43

c. American Correctional Association 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, 2-CO-1F-15

d. American Correctional Association Standards for Adult Correctional Boot Camp Programs: 1-ABC-1F-06, 1-ABC-1F-07, 1-ABC-1F-08, 1-ABC-1F-09, 1-ABC-4E-49

6. **DEFINITIONS**

a. **Research** means a systematic investigation, including development, testing, and evaluation, which is designed to develop or contribute to general knowledge.

Routine statistical tabulations and program reviews undertaken by Bureau employees for administrative purposes only and library research papers are not defined as research projects. Program evaluations, other than for program review purposes, are considered research projects.

b. **Institutional Review Board (IRB)** means a committee which reviews and monitors research and has membership requirements specified in this Program Statement and in 28 CFR part 46. The Bureau Research Review Board located in the Central Office is an IRB. Some local research review boards in Bureau institutions are IRBs if they meet the membership requirements.

c. **Local Research Review Board (LRRB)** means an institution research committee which reviews and monitors research at a Bureau institution. It may or may not qualify as an IRB, depending on the composition of the board.

d. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

e. **Employee** means a member of the Bureau staff or a consultant under contract who performs duties in furtherance of an agency function. Federal employees assigned to the Bureau (for example, Federal Prison Industries and Public Health Service employees) are included in the definition.

f. A **researcher** is a person who has met the qualifications of this Program Statement and has received approval from the Director, Bureau of Prisons, to conduct a research project within the Bureau.

7. **[REQUIREMENTS FOR RESEARCH PROJECTS AND RESEARCHERS §512.11**

a. Except as provided for in paragraph (b) of this section, the Bureau requires the following:

(1) In all research projects the rights, health, and human dignity of individuals involved must be respected.

(2) The project must have an adequate research design and contribute to the advancement of knowledge about corrections.

(3) The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.]

For more information on medical experimentation and pharmaceutical testing, consult the Health Services Manual.

[(4) The project must minimize risk to subjects; risks to subjects must be reasonable in relation to anticipated benefits. The selection of subjects within any one institution must be equitable. When applicable, informed consent must be sought and documented (see §§512.15 and 512.16).]

Informed consent would not be necessary, for example, when Bureau employees are analyzing only archival information in Bureau records.

28 CFR 512.15 and 512.16 refer to Sections 12 and 13, respectively, in this Program Statement.

[(5) Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:

(i) no longer in Bureau of Prisons custody, and
(ii) participating in authorized research being conducted by Bureau employees or contractors.]

The intent of limiting incentives is to ensure that participation of current inmates is completely voluntary. The inclusion of former inmates, however, may be helpful in addressing such issues as recidivism and program effectiveness.

Monetary rewards would be considered nominal if they do not exceed twice the minimum wage for each hour of the subject's expected participation in the research activity. Under special circumstances other reasonable incentives could be offered.

Steps may be considered by the Bureau to prevent confined prisoners from being placed at a disadvantage when they elect to participate in a research project. For example, work schedules might be rearranged to allow an inmate to participate.

[(6) The researcher must have academic preparation or experience in the area of study of the proposed research.

(7) The researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.

(8) Except as noted in the informed consent statement 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 pertains.

(9) The researcher must adhere to applicable provisions of the Privacy Act of 1974 and regulations pursuant to this Act.

(10) The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.]

The chairperson of the institution's LRRB shall inform any non-employees authorized to conduct research of applicable institution rules and regulations.

[(11) Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of this rule.]

See the Researcher Statement form BP-S604, available on BOPDOCS.

[(12) Except for computerized data records maintained at an official

Department of Justice site, records which contain nondisclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

(13) If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE), but the study is not a joint project involving ORE, the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.]

If the study is a joint project between the ORE and a researcher, the researcher may share individually identifiable data being collected with ORE. If the study is not a joint project, ORE may not proceed with analysis of the research data until ORE's proposed project has been approved under this Program Statement.

[(14) The researcher must submit planned methodological changes in a research project to the IRB for approval, and may be required to revise study procedures in accordance with the new methodology.]

A new methodology may require, for example, that the researcher revise the informed consent statement to reflect the changes.

[b. Requests from Federal agencies, the Congress, the Federal judiciary, or State or local governments to collect information about areas for which they are responsible and requests by private organizations for organizational rather than personal information from Bureau staff shall be reviewed by ORE to determine which provisions of this rule may be waived without jeopardizing the safety of human subjects. ORE shall document in writing the waiver of any specific provision along with the justification.]

8. **[CONTENT OF RESEARCH PROPOSAL § 512.12. When submitting a research proposal, the applicant shall provide the following information:**

a. A summary statement which includes:

(1) Name(s) and current affiliation(s) of the researcher(s);
(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) Number of subjects (staff/inmates) required and amount of time required from each; and
(9) Indication of risk or discomfort involved as a result of participation.

b. A comprehensive statement which includes:

(1) Review of related literature;]

Bureau employees should include references to similar studies by other Bureau components;

[(2) Detailed description of the research method;

(3) Significance of anticipated results and their contribution to the advancement of knowledge;

(4) Specific resources required from the Bureau;

(5) 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;

(6) Description of steps taken to minimize any risks described in (b)(5) of this section.

(7) Description of physical and/or administrative procedures to be followed to:

(a) ensure the security of any individually identifiable data that are being collected for the project, and

(b) destroy research records or remove individual identifiers from those records when the research has been completed.

(8) Description of any anticipated effects of the research project on institutional programs and operations; and

(9) Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.

c. A statement regarding assurances and certification required by 28 CFR part 46, if applicable.]

9. **[INSTITUTIONAL REVIEW BOARD §512.13**

a. The Bureau of Prisons' central institutional review board shall be called the Bureau Research Review Board (BRRB). It shall consist of the Chief, ORE, at least four other members, and one alternate, appointed by the Director, and shall meet a sufficient number of times to insure that each project covered by 28 CFR part 46 receives an annual review. A majority of members shall not be Bureau employees. The BRRB shall include an individual with legal expertise and a representative for inmates whom the Director determines is able to identify with inmate concerns and evaluate objectively a research proposal's impact on, and relevance to, inmates and to the correctional process.]

Members shall have varying backgrounds and shall not be associated, directly or indirectly, with the conduct of the research. The BRRB shall include:

- At least one scientist,
- One non-scientist who must be present at all meetings,
- Members of different racial/cultural groups, and
- Members of both genders.

- Generally, the representative for inmates shall be a chaplain with experience in correctional settings, and the individual with legal expertise shall be from the Bureau's Office of General Counsel.

- The alternate member shall serve when a conflict of interest prevents another member from reviewing a research proposal.

- Employee Union participation shall be in accordance with the Master Agreement and Local Supplemental Agreement provisions dealing with Union participation on institution committees.

[b. The Chief, ORE, shall serve as chairperson of the BRRB. If a potential conflict of interest exists for the BRRB chairperson on a particular research proposal, the Assistant

Director, Information, Policy, and Public Affairs Division, shall appoint another individual to serve as chairperson on matters pertaining to that project.]

A conflict of interest may arise, for example, when an ORE staff member submits a research proposal for approval.

10. **[SUBMISSION AND PROCESSING OF PROPOSAL §512.14**

a. An applicant may submit a preliminary research proposal for review by the Office of Research and Evaluation, Federal Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. Staff response to the preliminary proposal does not constitute a final decision.

b. If the study is to be conducted at only one institution, the applicant shall submit a formal proposal to the Warden of that institution. Proposal processing will be as follows:

(1) The Warden shall appoint a local research review board to consult with operational staff, to evaluate the proposal for compliance with research policy, and to make recommendations to the Warden. The local research review board is encouraged, but not required, to meet the membership requirements of an IRB, as specified in 28 CFR part 46.]

The following LRRB requirements are not sufficient for the board to qualify as an IRB:

- Unless the Warden specifies otherwise, the chief psychologist shall serve as chairperson of the LRRB.
- Representatives of departments that will be involved directly or indirectly in the research project at the institution shall serve as consultants to the LRRB.
- Employee Union participation shall be in accordance with the Master Agreement and Local Supplemental Agreement provisions dealing with Union participation on institution committees.

Those institutions which permit more than one research project each year are especially encouraged to establish an LRRB that meets the membership requirements of an IRB as specified in 28 CFR part 46. Under this regulation, the Warden would appoint at least five members (not all men or all women) with culturally diverse backgrounds, as follows:

- One of whom is not affiliated with the institution,
- One whose primary concerns are in scientific areas,
- One whose primary concerns are in nonscientific areas, and
- One, such as the chaplain, who should be prepared to represent

the concerns of prisoners.

If a proposed research project is covered by 28 CFR 46, but an institution's LRRB does not meet the membership requirements of an IRB, then the BRRB (in the Central Office) shall serve as the IRB. In that case, the BRRB chairperson shall appoint a person to represent institution concerns on the BRRB.

[(2) The Warden shall review the comments of the board, make a recommendation regarding the proposal, and forward the proposal package to the Regional Director, with a copy to the Chief, ORE.]

A completed Research Proposal Processing form BP-S605, available on BOPDOCS, shall be included in the proposal package.

[(3) The Regional Director shall review the proposal and forward recommendations to the Chief, ORE.]

The recommendations shall be included on the Research Proposal Processing form.

[c. If the study is to be conducted at more than one institution or at any other Bureau location, the applicant shall submit the research proposal to the Chief, Office of Research and Evaluation, Federal Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. The Chief, ORE, shall determine an appropriate review process.]

Applicants who are Bureau employees shall initiate the review process at their site of employment and obtain their Chief Executive Officer's recommendation before forwarding the proposal package to the Chief, ORE.

[d. All formal proposals will be reviewed by the BRRB.

e. The BRRB chairperson may exercise the authority of the full BRRB under an expedited review process when another official IRB (either within or outside the Bureau) has approved the research, or when, in his/her judgment, the research proposal meets the minimal risk standard and involves only the following:

(1) the study of existing data, documents, or records; and/or

(2) the study of individual or group behavior or characteristics of individuals, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. Such research would include test development and studies of perception, cognition, or game theory.]

Expedited review is an option for the BRRB or an IRB only, not for LRRBs which do not meet the IRB membership requirements of 28 CFR part 46.

[If a proposal is processed under expedited review, the BRRB chairperson must document in writing the reason for that determination.

f. The Chief, ORE, shall review all recommendations made and shall submit them in writing to the Director, Bureau of Prisons.

g. The Director, Bureau of Prisons, has final authority to approve or disapprove all research proposals. The Director may delegate this authority to the Assistant Director, Information, Policy, and Public Affairs Division.

h. The approving authority shall notify in writing the involved region(s), institution(s), and the prospective researcher of the final decision on a research proposal.]

If the Director plans a specific research project for management purposes and if the project is exempt from 28 CFR 46, the full approval process described in this Program Statement is not required because the approving authority has ordered that the research be conducted.

However, the prospective researcher must submit the proposal to the Chief, ORE, who shall review it for compliance with this Program Statement's other research requirements. The Chief, ORE, shall notify the prospective researcher and institutions and regions that will be actively involved in the project of the results of the review.

In some research projects that involve many institutions, Wardens may not have had the opportunity to review the project proposal before it was formally approved.

Therefore, prior to implementation of any research project at a specific institution, the Warden at that institution shall have an opportunity to:

- Review the project,
- Consult with the local research review board, and,
- If necessary, request reconsideration by the Director, through the Chief, ORE.

The Director may terminate the project at that institution, as provided in Section 15 of this Program Statement.

11. **EMPLOYEES AS SUBJECTS.** Employee participation as subjects shall be in accordance with the Master Agreement, Federal Bureau of Prisons, Council of Prison Locals, American Federation of Government Employees provisions dealing with the administration of tests and questionnaires to employees.

12. **[ACCESS TO BUREAU OF PRISONS RECORDS §512.15**

a. Employees, including consultants, of the Bureau who are conducting authorized research projects 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 Bureau is limited in access to information available under the Freedom of Information Act (5 U.S.C. 552).]

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

[c. A non-employee of the Bureau 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 (5 U.S.C. 552a(b)(5)).]

13. **[INFORMED CONSENT §512.16**

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 will 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 may not guarantee confidentiality when the subject indicates an intent to commit future criminal conduct or harm himself/herself or someone else, or, if the subject is an inmate, indicates an 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; and

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

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

Most research by employees will be conducted under the general authority of 18 U.S.C. 4001(b) and 4042(a), which enable the Bureau to conduct research on the correctional environment.

The researcher may use the Informed Consent/Consent to Release

Information For Research form BP-S606, available on BOPDOCS, as a guide.

[c. A researcher who is an employee of the Bureau, 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) The Chief, ORE, determines the research project or data-collection instrument is of a sensitive nature.]

A researcher who is a Bureau employee is exempt from informed consent requirements when the research involves archival data analysis exclusively and does not require direct (active) inmate participation.

[d. A researcher who is a non-employee of the Bureau, 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. The researcher may 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 or that there is significantly more risk to the subject if the statement is signed. The signed statement shall be submitted to the chairperson of the appropriate local research review board.]

The original of any signed consent form shall be placed in the specific research project's file at the institution where the research is conducted. The file shall be easily accessible to the LRRB. A copy of any signed consent form which grants a researcher access to an Inmate's Central File shall be placed in the non-disclosable portion of the Inmate Central File and a copy shall be offered to the inmate.

14. **[MONITORING APPROVED RESEARCH PROJECTS §512.17. The BRRB shall monitor all research projects for compliance with Bureau policies. At a minimum, yearly reviews will be conducted.]**

At an institution, the members of the LRRB shall assist by providing information on research projects to the BRRB.

After a project begins, staff shall refer any matters of concern to Bureau staff or subjects to the appropriate research review board chairperson and the researcher.

An institution's research review board members shall report any violations of research policy to the appropriate Warden and regional director, the chairperson of the BRRB, and the Director, Bureau of Prisons.

15. **[TERMINATION OR SUSPENSION §512.18. The Director, Bureau of Prisons, may 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 institution.]**

16. **RECORD-KEEPING.** In accordance with the requirements of 28 CFR part 46, the BRRB shall maintain a file on each research project covered by those regulations. The appropriate local research review boards shall also keep research project files for at least three years following receipt of a final report and/or any findings resulting from the research.

a. The BRRB file shall include:

(1) A copy of the original research proposal;

(2) A record of any materials related to the proposal's:

- Approval,
- Disapproval,
- Methodological change,
- Progress report,
- Monitoring,
- Suspension,
- Termination, and
- Publication of results;

(3) Any record of an individual's participation required to be maintained by this Program Statement consistent with the informed consent requirements of Bureau directives;

(4) Minutes of BRRB meetings at which any action concerning the research project was taken. The minutes shall include:

- Attendance at meetings;

- A record of any actions taken, including votes for, against, and abstaining concerning any research proposal;

- The basis for requiring changes to or disapproving a research project; and

- A summary of any discussion of a significant issue related to a research project.

(5) Any other memoranda or information relevant to any decisions about the research project.

b. The LRRB file shall contain materials pertaining to the processing of the proposal at that location and the original or copies of signed informed consent statements.

17. **[REPORTS §512.19. The researcher shall prepare reports of progress on the research and at least one report of findings.**

a. At least once a year, the researcher shall provide the Chief, ORE, with a report on the progress of the research.

**b. At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the BRRB,
the Regional Director, and the Warden of each institution which provided data or assistance. The researcher shall include an abstract in the report of findings.]**

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

18. **[PUBLICATION OF RESULTS OF RESEARCH PROJECT § 512.20**

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

(1) In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.

(2) The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

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 Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.]

19. **[COPYRIGHT PROVISIONS §512.21**

a. An employee of the Bureau may not copyright any work prepared as part of his/her official duties.

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

c. Subject to a royalty-free, non-exclusive, and irrevocable license, which the Bureau of Prisons 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.]

/s/
Kathleen Hawk Sawyer
Director