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may be conducted by staff members of the opposite sex only in emergency situations with the Warden's authorization.

(c) *Visual Search.* You and your belongings may be visually searched as follows:

(1) *Person.* (i) A visual search of your person involves removing all articles of clothing, including religious headwear, to allow a visual (non-tactile) inspection of your body surfaces and cavities.

(ii) Visual searches of your person must always be authorized by the Warden or his/her designee and based on reasonable suspicion; random visual searches are prohibited.

(iii) When authorized, visual searches will be performed discreetly, in a private area away from others, and by staff members of the same sex as the non-inmate being searched. Visual searches may be conducted by staff members of the opposite sex in emergency situations with the Warden's authorization.

(iv) Body cavity (tactile) searches of non-inmates are prohibited.

(2) *Belongings.* A visual search of your belongings involves opening and exposing all contents for visual and manual inspection, and may be done either as part of a random search or with reasonable suspicion.

(d) *Drug Testing.* (1) You may be tested for use of intoxicating substances by any currently reliable testing method, including, but not limited to, breathalyzers and urinalysis.

(2) Drug testing must always be authorized by the Warden or his/her designee and must be based on reasonable suspicion that you are under the influence of an intoxicating substance upon entering, or while inside, a Bureau facility or Bureau grounds.

(3) Searches of this type will always be performed discreetly, in a private area away from others, and by staff members adequately trained to perform the test. Whenever possible, urinalysis tests will be conducted by staff members of the same sex as the non-inmate being tested. Urinalysis tests may be conducted by staff members of the opposite sex only in emergency situations with the Warden's authorization.

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§511.17 When a non-inmate will be denied entry to or required to leave a Bureau facility or Bureau grounds.

At the Warden's, or his/her designee's, discretion, and based on this subpart, you may be denied entry to, or required to leave, a Bureau facility or Bureau grounds if:

(a) You refuse to be searched under this subpart; or

(b) There is reasonable suspicion that you may be engaged in, attempting, or about to engage in, prohibited activity that jeopardizes the Bureau's ability to ensure the safety, security, and orderly operation of its facilities, or protect the public. "Reasonable suspicion," for this purpose, may be based on the results of a search conducted under this subpart, or any other reliable information.

§511.18 When Bureau staff can arrest and detain a non-inmate.

(a) You may be arrested and detained by Bureau staff anytime there is probable cause indicating that you have violated or attempted to violate applicable criminal laws while at a Bureau facility, as authorized by 18 U.S.C. 3050.

(b) "Probable cause" exists when specific facts and circumstances lead a reasonably cautious person (not necessarily a law enforcement officer) to believe a violation of criminal law has occurred, and warrants consideration for prosecution.

(c) Non-inmates arrested by Bureau staff under this regulation will be physically secured, using minimally necessary force and restraints, in a private area of the facility away from others. Appropriate law enforcement will be immediately summoned to investigate the incident, secure evidence, and commence criminal prosecution.

PART 512—RESEARCH

Subpart A [Reserved]

Subpart B—Research

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- 512.21 Copyright provisions.

AUTHORITY: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 5006-5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; 28 CFR 0.95-0.99.

Subpart A [Reserved]

Subpart B—Research

SOURCE: 59 FR 13860, Mar. 23, 1994, unless otherwise noted.

§ 512.10 Purpose and scope.

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 subpart, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

[59 FR 13860, Mar. 23, 1994, as amended at 62 FR 6661, Feb. 12, 1997]

§ 512.11 Requirements for research projects and researchers.

(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.

(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).

(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.

(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

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office in which the research is conducted.

(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 subpart.

(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.

(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.

(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 subpart 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.

[62 FR 6661, Feb. 12, 1997]

§512.12 Content of research proposal.

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;
- (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:

- (i) Ensure the security of any individually identifiable data that are being collected for the project, and
- (ii) 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.

§512.13 Institutional Review Board.

(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

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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.

(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.

§ 512.14 Submission and processing of proposal.

(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.

(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.

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

(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.

(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. 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.

[59 FR 13860, Mar. 23, 1994, as amended at 62 FR 6661, Feb. 12, 1997]

§ 512.15 Access to Bureau of Prisons records.

(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).

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(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)).

§512.16 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 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.

(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.

(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.

§512.17 Monitoring approved research projects.

The BRRB shall monitor all research projects for compliance with Bureau policies. At a minimum, yearly reviews will be conducted.

§512.18 Termination or suspension.

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.

§512.19 Reports.

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.

§ 512.20 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 subpart.

(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 subpart, 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.

[59 FR 13860, Mar. 23, 1994, as amended at 62 FR 6662, Feb. 12, 1997]

§ 512.21 Copyright provisions.

(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 subpart, 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 subpart.

(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 mate-

rials developed as a result of research conducted under this subpart.

[59 FR 13860, Mar. 23, 1994, as amended at 62 FR 6662, Feb. 12, 1997]

PART 513—ACCESS TO RECORDS

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