

Bureau of Prisons, Justice

§ 512.11

- 512.14 Submission and processing of proposal.
- 512.15 Access to Bureau of Prisons records.
- 512.16 Informed consent.
- 512.17 Monitoring approved research projects.
- 512.18 Termination or suspension.
- 512.19 Reports.
- 512.20 Publication of results of research project.
- 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AUTHORITY: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 5006-5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; 28 CFR 0.95-0.99.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