PART 512—RESEARCH

Subpart A [Reserved]

Subpart B—Research

Sec.

AUTHORITY: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; 28 CFR 0.95–0.99.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