DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 512

[BOP–1008–F]

RIN 1120–AA14

Research

AGENCY: Bureau of Prisons, Justice.

ACTION: Finalization of Interim Rule.

SUMMARY: In this document, the Bureau of Prisons is finalizing its interim regulations on Research. In response to public comment the Bureau is modifying its provisions for expedited review. For the sake of administrative efficiency, the Bureau is also streamlining review procedures for certain types of research requests.

EFFECTIVE DATE: February 12, 1997.

ADDRESSES: Office of General Counsel, Bureau of Prisons, HOLC Room 754, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Office of General Counsel, Bureau of Prisons, phone (202) 514–6655.

SUPPLEMENTARY INFORMATION: The Bureau of Prisons (Bureau) is finalizing its regulations on Research. An interim rule on this subject was published in the Federal Register March 23, 1994 (59 FR 13860).

The Bureau received comment from a university and from a professional organization. The commenters expressed concern that the provisions in § 512.11 (b) and (c) which require that a project contribute to the advancement of knowledge about corrections and which prescribe projects involving medical experimentation, cosmetic research, or pharmaceutical testing ''could serve to place at risk individual prisoners with medical problems.'' The commenters argued that, ''[i]n some cases, the only avenue for treating prisoners with diseases for which there are no alternative treatments or for which the standard of care has numerous side effects may be to enroll them in a clinical trial involving an experimental drug, device or procedure.'' The commenters further argued, on general principles, that excluding a class of subjects (i.e., prisoners) from participation in research which has potential direct benefit to them was unfair. The commenters noted that ''[t]he provisions as currently written appear to assume that participation in research is a 'burden' and do not take into account that for individual prisoners there may be real benefits of participating in medical research.''

The Bureau is strongly committed to its policy that medical experimentation or pharmaceutical testing may not be conducted on inmates in a research project. If a researcher initiated a request for inmate participation in medical experimentation or pharmaceutical testing, participation would not be permitted. The concerns raised by the commenters for the treatment of individual prisoners with medical problems are addressed under the Bureau's medical policy which follows standard medical protocols. The Bureau's medical policy does not preclude the use of U.S. Department of Health and Human Services-approved clinical trials that may be warranted for diagnosis or treatment of a specific inmate when recommended by the responsible physician and approved by the Medical Director. Consistent with standard medical protocols, such measures must have the prior written consent of the patient (i.e., the inmate) and must be conducted under conditions approved by the Department of Health and Human Services. Therefore, the Bureau believes that no modification of its policy on research is necessary.

The commenters also requested clarification on the relationship between the Bureau's regulations and the Department of Justice's requirements on research found in 28 CFR part 46. More specifically, the commenters asked whether the Bureau Research Review Board (BRRB) and the local research review boards will be expected to comply with the requirements of Justice's regulations, noting as an example that Justice's regulations required project review appropriate to the degree of risk but not less than once per year, while the Bureau's ''interim rule refers to yearly reviews.'' With respect to reviews of approved research, the Bureau notes that the wording in § 512.17 (''At a minimum, yearly reviews will be conducted'') paraphrases the Justice standard. In general, the BRRB meets the requirements specified in 28 CFR part 46; the Bureau's local research review boards are not required to meet those criteria and accordingly adhere to the provisions of the Bureau's regulations instead. The commenters also recommended that the Bureau's regulations be consistent with the Department of Health and Human Services' regulations in 45 CFR part 46, subpart C. The Department of Justice, when issuing its regulations, noted in the preamble that it intended to retain special (additional) protections for prison populations (56 FR 28012). The Bureau's provisions in 28 CFR part 512 serve this purpose. One protection is that the Bureau in 28 CFR part 512 requires a review of research proposals which are technically exempt from 28 CFR part 46. Some of the additional protections are similar to those in 45 CFR part 46, subpart C. With respect to the Bureau's additional protection for medical experimentation or pharmaceutical testing which is not present in 28 CFR part 46 or in subpart C of 45 CFR part 46, the Bureau received no adverse comment on this point from either the Department of Justice or the Department of Health and Human Services.

The commenters questioned whether expedited review would be possible under § 512.14(e) for modifications to a research project. The provisions in § 512.14(e) govern the conditions under which expedited review is possible. The requirement to submit planned methodological changes in a research project is contained in § 512.11(n). The intent of these provisions is that these changes can be approved by either the full Board or through expedited review depending upon the impact of the changes in the methodology on the subjects in the study.

Finally, the commenters urged the Bureau to obtain a Department of Health and Human Services ''assurance'' for its BRRB so that the BRRB could review research proposals in place of the research organization's Institution Review Board (IRB). The Bureau is not eligible to obtain a Multiple Project Assurance with the Department of Health and Human Services. Therefore, the Bureau's IRBs cannot officially substitute for an HHS-approved IRB. However, the Bureau is modifying its interim regulations to allow for both review of non-HHS-funded research by the BRRB and expedited review of research projects by the BRRB in place of the research organization's IRB if the research has been approved by another official IRB (either within or outside the Bureau).

In adopting the interim rules as final, the Bureau wishes to update an address contained in the regulations and to make one further change in order to streamline procedures for approval or disapproval of (1) information requests from Federal agencies, the Congress, the Federal judiciary, or State or local governments, and (2) requests by private organizations for organizational rather than personal information from Bureau staff. To this effect, the provisions in § 512.11 have been recodified within paragraph (a) and a new paragraph (b) has been added to specify that 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 the Office of Research and Evaluation to determine which requirements may be waived without jeopardizing human subject protections and to document the actual waiver of any specific provisions. The address for the Office of Research and Evaluation, which appears in paragraphs (a) and (c) of § 512.14, is being modified to remove the obsolete room reference ''202 NALC Building'.

Members of the public may submit comment concerning this rule by writing the previously cited address. These comments will be considered but will receive no response in the Federal Register.

The Bureau of Prisons has determined that this rule is not a significant regulatory action for the purpose of E.O. 12866, and accordingly this rule was not reviewed by the Office of Management and Budget pursuant to E.O. 12866. After review of the law and regulations, the Director, Bureau of Prisons has certified that this rule, for the purpose of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), does not have a significant economic impact on a substantial number of small entities, within the meaning of the Act. The economic impact of the Bureau's interim provisions on Research is primarily determined by the existing requirements of the Federal government's common regulations for the protection of human subjects (see 28 CFR part 46 and 45 CFR part 46). The modifications to the Bureau's previously published interim procedures further serve to reduce the economic impact of these provisions in certain cases.

List of Subjects in 28 CFR Part 512

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

Kathleen M. Hawk,

Director, Bureau of Prisons.

Accordingly, pursuant to the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons in 28 CFR 0.96(p), the interim rule which was published at 59 FR 13860 on March 23, 1994, is adopted as final with the following changes.

SUBCHAPTER A—GENERAL MANAGEMENT AND ADMINISTRATION

PART 512—RESEARCH

1. The authority citation for 28 CFR part 512 continues to read as follows:

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.

2. Section 512.11 is revised to read as follows:

§ 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.

3. In § 512.14, paragraphs (a) and (c) are amended by removing the phrase ''202 NALC Building,'', and the introductory text of paragraph (e) is revised to read as follows:

§ 512.14 Submission and processing of proposal.

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(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:

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§§ 512.10, 512.20, 512.21 [Amended]

4. In addition to the amendments set forth above, in 28 CFR part 512, subpart B, remove the words ''this rule'' and add, in their place, the words ''this subpart'' in the following places:

(a) Section 512.10;

(b) Section 512.20(a) introductory text and (b);

(c) Section 512.21 (b) and (c).

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