

Bureau of Prisons, Justice

§ 512.16

(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).

(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;

§512.17

(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

28 CFR Ch. V (7-1-05 Edition)

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