

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;