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.

§ 512.13 Institutional Review Board.

(a) The Bureau of Prisons' central institutional review board shall be called the Bureau Research Review Board (BRRB). It shall consist of the Chief, ORE, at least four other members, and one alternate, appointed by the Director, and shall meet a sufficient number of times to insure that each project covered by 28 CFR part 46 receives an annual review. A majority of members shall not be Bureau employees. The BRRB shall include an individual with legal expertise and a representative for inmates whom the Director determines is able to identify with inmate concerns and evaluate objectively a research proposal's impact on, and relevance to, inmates and to the correctional process.

(b) The Chief, ORE, shall serve as chairperson of the BRRB. If a potential conflict of interest exists for the BRRB chairperson on a particular research proposal, the Assistant Director, Information, Policy, and Public Affairs Division, shall appoint another individual to serve as chairperson on matters pertaining to that project.

§ 512.14 Submission and processing of proposal.

(a) An applicant may submit a preliminary research proposal for review by the Office of Research and Evaluation, Federal Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. Staff response to the preliminary proposal does not constitute a final decision.

(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;