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.