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(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;

(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 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.

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(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 conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

[59 FR 13860, Mar. 23, 1994, as amended at 62 FR 6662, Feb. 12, 1997]

§ 512.21 Copyright provisions.

(a) An employee of the Bureau may not copyright any work prepared as part of his/her official duties.

(b) As a precondition to the conduct of research under this subpart, a non-employee shall grant in writing to the Bureau a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, translate, and otherwise use and authorize others to publish and use original materials developed as a result of research conducted under this subpart.

(c) Subject to a royalty-free, non-exclusive and irrevocable license, which the Bureau of Prisons reserves, to reproduce, publish, translate, and otherwise use and authorize others to publish and use such materials, a non-employee may copyright original mate-

rials developed as a result of research conducted under this subpart.

[59 FR 13860, Mar. 23, 1994, as amended at 62 FR 6662, Feb. 12, 1997]

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