(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.