

APPENDIX A
TITLE 28 CODE OF FEDERAL REGULATIONS

- 1. Part 46: *Protection of Human Subjects***
- 2. Part 22: *Protection of Confidentiality of Identifiable Research***

1. Part 46: Protection of Human Subjects

TITLE 28 – JUDICIAL ADMINISTRATION PART 46 – PROTECTION OF HUMAN SUBJECTS

Sec. 46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in Sec. 46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in Sec. 46.102(e) must be reviewed and approved, in compliance with Sec. 46.101, Sec. 46.102, and Sec. 46.107 through Sec. 46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

- (i) research on regular and special education instructional strategies, or
- (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- (i) Public benefit or service programs;
- (ii) Procedures for obtaining benefits or services under those programs;
- (iii) Possible changes in or alternatives to those programs or procedures;

or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) If wholesome foods without additives are consumed or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services

(HHS), and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures.¹

Sec. 46.102 Definitions.

(a) Department or agency head means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) Institution means any public or private entity or agency (including federal, state, and other agencies).

(c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or nonresearch in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

¹ Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A-D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. [56 FR 28012 and 28020, June 18, 1991; 56 FR 29756, June 28, 1991]

(g) IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Secs. 46.104-46.106 [Reserved]

Sec. 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Sec. 46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in Sec. 46.103(b)(4) and, to the extent required by, Sec. 46.103(b)(5).

(b) Except when an expedited review procedure is used (see Sec. 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Sec. 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 46.116. The IRB may require that information, in addition to that specifically mentioned in Sec. 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with Sec. 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Sec. 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

Sec. 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Sec. 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by Sec. 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Sec. 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

Sec. 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Sec. 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in Sec. 46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in Sec. 46.103(b)(4) and Sec. 46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by Sec. 46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - (i) Public benefit of service programs;
 - (ii) Procedures for obtaining benefits or services under those programs;
 - (iii) Possible changes in or alternatives to those programs or procedures;

or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by Sec. 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by Sec. 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under Sec. 46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

Sec. 46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

Sec. 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one. [56 FR 28012, 28020, June 18, 1991, as amended at 61 FR 33658, June 28, 1996]

Sec. 46.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

Sec. 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

Sec. 46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

2. Part 22: “Protection of Confidentiality of Identifiable Research”

TITLE 28 – JUDICIAL ADMINISTRATION PART 22 – CONFIDENTIALITY OF IDENTIFIABLE RESEARCH AND STATISTICAL INFORMATION

Sec. 22.1 Purpose.

The purpose of these regulations is to:

- (a) Protect privacy of individuals by requiring that information identifiable to a private person obtained in a research or statistical program may only be used and/or revealed for the purpose for which obtained;
- (b) Insure that copies of such information shall not, without the consent of the person to whom the information pertains, be admitted as evidence or used for any purpose in any judicial or administrative proceedings;
- (c) Increase the credibility and reliability of federally-supported research and statistical findings by minimizing subject concern over subsequent uses of identifiable information;
- (d) Provide needed guidance to persons engaged in research and statistical activities by clarifying the purposes for which identifiable information may be used or revealed; and
- (e) Insure appropriate balance between individual privacy and essential needs of the research community for data to advance the state of knowledge in the area of criminal justice.
- (f) Insure the confidentiality of information provided by crime victims to crisis intervention counselors working for victim services programs receiving funds provided under the Crime Control Act, and Juvenile Justice Act, and the Victims of Crime Act. [41 FR 54846, Dec. 15, 1976, as amended at 51 FR 6400, Feb. 24, 1986]

Sec. 22.2 Definitions.

- (a) Person means any individual, partnership, corporation, association, public or private organization or governmental entity, or combination thereof.
- (b) Private person means any person defined in Sec. 22.2(a) other than an agency, or department of Federal, State, or local government, or any component or combination thereof included as a private person is an individual acting in his or her official capacity.
- (c) Research or statistical project means any program, project, or component thereof which is supported in whole or in part with funds appropriated under the Act and whose purpose is to develop, measure, evaluate, or otherwise advance the state of knowledge in a particular area. The term does not include “intelligence” or other information-gathering activities in which information pertaining to specific individuals is obtained for purposes directly related to enforcement of the criminal laws.
- (d) Research or statistical information means any information which is collected during the conduct of a research or statistical project and which is intended to be utilized for research or statistical purposes. The term includes information which is collected directly from the individual or obtained from any agency or individual having possession, knowledge, or control thereof.
- (e) Information identifiable to a private person means information which either –
 - (1) Is labelled by name or other personal identifiers, or
 - (2) Can, by virtue of sample size or other factors, be reasonably interpreted as referring to a particular private person.
- (f) Recipient of assistance means any recipient of a grant, contract, interagency agreement, subgrant, or subcontract under the Act and any person, including subcontractors, employed by such recipient in connection with performances of the grant, contract, or interagency agreement.

(g) Officer or employee of the Federal Government means any person employed as a regular or special employee of the U.S. (including experts, consultants, and advisory board members) as of July 1, 1973, or at any time thereafter.

(h) The act means the Omnibus Crime Control and Safe Streets Act of 1968, as amended.

(i) Applicant means any person who applies for a grant, contract, or subgrant to be funded pursuant to the Act.

(j) The Juvenile Justice Act means the “Juvenile Justice and Delinquency Prevention Act of 1974, as amended.”

(k) The Victims of Crime Act means the Victims of Crime Act of 1984. [41 FR 54846, Dec. 15, 1976, as amended at 43 FR 16974, Apr. 21, 1978; 51 FR 6400, Feb. 24, 1986]

Sec. 22.20 Applicability.

(a) These regulations govern use and revelation of research and statistical information obtained, collected, or produced either directly by BJA, OJJDP, BJS, NIJ, or OJP or under any interagency agreement, grant, contract, or subgrant awarded under the Crime Control Act, the Juvenile Justice Act, and the Victims of Crime Act.

(b) The regulations do not apply to any records from which identifiable research or statistical information was originally obtained; or to any records which are designated under existing statutes as public; or to any information extracted from any records designated as public.

(c) The regulations do not apply to information gained regarding future criminal conduct. [41 FR 54846, Dec. 15, 1976, as amended at 43 FR 16974, Apr. 21, 1978; 51 FR 6400, 6401, Feb. 24, 1986]

Sec. 22.21 Use of identifiable data.

Research or statistical information identifiable to a private person may be used only for research or statistical purposes.

Sec. 22.22 Revelation of identifiable data.

(a) Except as noted in paragraph (b) of this section, research and statistical information relating to a private person may be revealed in identifiable form on a need-to-know basis only to—

(1) Officers, employees, and subcontractors of the recipient of assistance;

(2) Such individuals as needed to implement sections 202(c)(3), 801, and 811(b) of the Act; and sections 223(a)(12)(A), 223(a)(13), 223(a)(14), and 243 of the Juvenile Justice and Delinquency Prevention Act.

(3) Persons or organizations for research or statistical purposes. Information may only be transferred for such purposes upon a clear demonstration that the standards of Sec. 22.26 have been met and that, except where information is transferred under paragraphs (a)(1) and (2) of this section, such transfers shall be conditioned on compliance with a Sec. 22.24 agreement.

(b) Information may be revealed in identifiable form where prior consent is obtained from an individual or where the individual has agreed to participate in a project with knowledge that the findings cannot, by virtue of sample size, or uniqueness of subject, be expected to totally conceal subject identity. [41 FR 54846, Dec. 15, 1976, as amended at 51 FR 6400, Feb. 24, 1986]

Sec. 22.23 Privacy certification.

(a) Each applicant for BJA, OJJDP, BJS, NIJ, or OJP support either directly or under a State plan shall submit a Privacy Certificate as a condition of approval of a grant application or contract proposal which has a research or statistical project component under which information identifiable to a private person will be collected.

(b) The Privacy Certificate shall briefly describe the project and shall contain assurance by the applicant that:

(1) Data identifiable to a private person will not be used or revealed, except as authorized under Secs. 22.21, 22.22.

(2) Access to data will be limited to those employees having a need therefore and that such persons shall be advised of and agree in writing to comply with these regulations.

(3) All subcontracts which require access to identifiable data will contain conditions meeting the requirements of Sec. 22.24.

(4) To the extent required by Sec. 22.27 any private persons from whom identifiable data are collected or obtained, either orally or by means of written questionnaire, shall be advised that the data will only be used or revealed for research or statistical purposes and that compliance with requests for information is not mandatory. Where the notification requirement is to be waived, pursuant to Sec. 22.27(c), a justification must be included in the Privacy Certificate.

(5) Adequate precautions will be taken to insure administrative and physical security of identifiable data.

(6) A log will be maintained indicating that identifiable data have been transmitted to persons other than BJA, OJJDP, BJS, NIJ, or OJP or grantee/contractor staff or subcontractors, that such data have been returned, or that alternative arrangements have been agreed upon for future maintenance of such data.

(7) Project plans will be designed to preserve anonymity of private persons to whom information relates, including, where appropriate, name-stripping, coding of data, or other similar procedures.

(8) Project findings and reports prepared for dissemination will not contain information which can reasonably be expected to be identifiable to a private person except as authorized under Sec. 22.22.

(c) The applicant shall attach to the Privacy Certification a description of physical and/or administrative procedures to be followed to insure the security of the data to meet the requirements of Sec. 22.25. [41 FR 5486, Dec. 15, 1976, as amended at 51 FR 6401, Feb. 24, 1986]

Sec. 22.24 Information transfer agreement.

Prior to the transfer of any identifiable information to persons other than BJA, OJJDP, BJS, NIJ, or OJP or project staff, an agreement shall be entered into which shall provide, as a minimum, that the recipient of data agrees that:

(a) Information identifiable to a private person will be used only for research and statistical purposes.

(b) Information identifiable to a private person will not be revealed to any person for any purpose except where the information has already been included in research findings (and/or data bases) and is revealed on a need-to-know basis for research or statistical purposes, provided that such transfer is approved by the person providing information under the agreement, or authorized under Sec. 22.24(e).

(c) Knowingly and willfully using or disseminating information contrary to the provisions of the agreement shall constitute a violation of these regulations, punishable in accordance with the Act.

(d) Adequate administrative and physical precautions will be taken to assure security of information obtained for such purpose.

(e) Access to information will be limited to those employees or subcontractors having a need therefore in connection with performance of the activity for which obtained, and that such persons shall be advised of, and agree to comply with, these regulations.

(f) Project plans will be designed to preserve anonymity of private persons to whom information relates, including, where appropriate, required name-stripping and/or coding of data or other similar procedures.

(g) Project findings and reports prepared for dissemination will not contain information which can reasonably be expected to be identifiable to a private person.

(h) Information identifiable to a private person (obtained in accordance with this agreement) will, unless otherwise agreed upon, be returned upon completion of the project for which obtained and no copies of that information retained. [41 FR 5486, Dec. 15, 1976, as amended at 51 FR 6401, Feb. 24, 1986]

Sec. 22.25 Final disposition of identifiable materials.

Upon completion of a research or statistical project the security of identifiable research or statistical information shall be protected by:

(a) Complete physical destruction of all copies of the materials or the identifiable portion of such materials after a three-year required recipient retention period or as soon as authorized by law, or

(b) Removal of identifiers from data and separate maintenance of a name-code index in a secure location.

The Privacy Certificate shall indicate the procedures to be followed and shall, in the case of paragraph (b) of this section, describe procedures to secure the name index.

Sec. 22.26 Requests for transfer of information.

(a) Requests for transfer of information identifiable to an individual shall be submitted to the person submitting the Privacy Certificate pursuant to Sec. 22.23.

(b) Except where information is requested by BJA, OJJDP, BJS, NIJ, or OJP, the request shall describe the general objectives of the project for which information is requested, and specifically justify the need for such information in identifiable form. The request shall also indicate, and provide justification for the conclusion that conduct of the project will not, either directly or indirectly, cause legal, economic, physical, or social harm to individuals whose identification is revealed in the transfer of information.

(c) Data may not be transferred pursuant to this section where a clear showing of the criteria set forth above is not made by the person requesting the data. [41 FR 5486, Dec. 15, 1976, as amended at 51 FR 6401, Feb. 24, 1986]

Sec. 22.27 Notification.

(a) Any person from whom information identifiable to a private person is to be obtained directly, either orally, by questionnaire, or other written documents, shall be advised:

(1) That the information will only be used or revealed for research or statistical purposes;

and

(2) That compliance with the request for information is entirely voluntary and may be terminated at any time.

(b) Except as noted in paragraph (c) of this section, where information is to be obtained through observation of individual activity or performance, such individuals shall be advised:

(1) Of the particular types of information to be collected;

(2) That the data will only be utilized or revealed for research or statistical purposes; and

(3) That participation in the project in question is voluntary and may be terminated at any time.

(c) Notification, as described in paragraph (b) of this section, may be eliminated where information is obtained through field observation of individual activity or performance and in the judgment of the researcher such notification is impractical or may seriously impede the progress of the research.

(d) Where findings in a project cannot, by virtue of sample size, or uniqueness of subject, be expected to totally conceal subject identity, an individual shall be so advised.
[Code of Federal Regulations]

Sec. 22.28 Use of data identifiable to a private person for judicial, legislative or administrative purposes.

(a) Research or statistical information identifiable to a private person shall be immune from legal process and shall only be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative or administrative proceeding with the written consent of the individual to whom the data pertains.

(b) Where consent is obtained, such consent shall:

(1) Be obtained at the time that information is sought for use in judicial, legislative or administrative proceedings;

(2) Set out specific purposes in connection with which information will be used;

(3) Limit, where appropriate, the scope of the information subject to such consent. [41 FR 54846, Dec. 15, 1976, as amended at 45 FR 62038, Sept. 18, 1980]

Sec. 22.29 Sanctions.

Where BJA, OJJDP, BJS, NIJ, or OJP believes that a violation has occurred of section 812(a) of the Act or section 1407(d) of the Victims of Crime Act, these regulations, or any grant or contract conditions entered into thereunder, it may initiate administrative actions leading to termination of a grant or contract, commence appropriate personnel and/or other procedures in cases involving Federal employees, and/or initiate appropriate legal actions leading to imposition of a fine of not to exceed \$10,000 against any person responsible for such violations. [41 FR 54846, Dec. 15, 1976, as amended at 45 FR 62038, Sept. 18, 1980; 51 FR 6401, Feb. 24, 1986]