

§ 1027.8

employee must receive written notice that CPSC has received a certified debt claim from the creditor agency, the amount of the debt, the date salary offset will begin, and the amount of the deduction(s). CPSC shall not review the merits of the creditor agency's determination of the validity or the amount of the certified claim.

(2) If the employee transfers to another agency after the creditor agency has submitted its debt claim to CPSC and before the debt is collected completely, CPSC must certify the amount collected. One copy of the certification must be furnished to the employee. A copy must be furnished to the creditor agency with notice of the employee's transfer.

§ 1027.8 Procedures for salary offset.

(a) Deductions to liquidate an employee's debt will be by the method and in the amount stated in the Executive Director's notice of intention to offset as provided in § 1027.4. Debts will be collected in one lump sum where possible. If the employee is financially unable to pay in one lump sum, collection must be made in installments.

(b) Debts will be collected by deduction at officially established pay intervals from an employee's current pay account unless alternative arrangements for repayment are made.

(c) Installment deductions will be made over a period not greater than the anticipated period of employment. The size of installment deductions must bear a reasonable relationship to the size of the debt and the employee's ability to pay. The deduction for the pay intervals for any period must not exceed 15% of disposable pay unless the employee has agreed in writing to a deduction of a greater amount.

(d) Unliquidated debts may be offset against any financial payment due to a separated employee including but not limited to final salary or leave payment in accordance with 31 U.S.C. 3716.

§ 1027.9 Refunds.

(a) CPSC will promptly refund to an employee any amounts deducted to satisfy debts owed to CPSC when the debt is waived, found not owed to CPSC, or when directed by an administrative or judicial order.

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(b) Another creditor agency will promptly return to CPSC any amounts deducted by CPSC to satisfy debts owed to the creditor agency when the debt is waived, found not owed, or when directed by an administrative or judicial order.

(c) Unless required by law, refunds under this paragraph shall not bear interest.

§ 1027.10 Statute of limitations.

(a) If a debt has been outstanding for more than 10 years after CPSC's right to collect the debt first accrued, the agency may not collect by salary offset unless facts material to the Government's right to collect were not known and could not reasonably have been known by the official or officials who were charged with the responsibility for discovery and collection of such debts.

(b) [Reserved]

§ 1027.11 Non-waiver of rights.

An employee's involuntary payment of all or any part of a debt collected under these regulations will not be construed as a waiver of any rights that the employee may have under 5 U.S.C. 5514 or any other provision of law.

§ 1027.12 Interest, penalties, and administrative costs.

Charges may be assessed on a debt for interest, penalties, and administrative costs in accordance with 31 U.S.C. 3717 and the Federal Claims Collection Standards, 4 CFR 101.1 *et seq.*

PART 1028—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

SOURCE: 56 FR 28012, 28019, June 18, 1991, unless otherwise noted.

§ 1028.101 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 § 1028.102(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 § 1028.102(e) must be reviewed and approved, in compliance with §§ 1028.101, 1028.102, and 1028.107 through 1028.117 of this pol-

icy, 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 Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.¹

[56 FR 28012, 28019, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

¹Institutions 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, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public