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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 §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.

§ 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.

§ 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 head 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]

§ 46.121 [Reserved]

§ 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.

§ 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).

§ 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.

PART 47—RIGHT TO FINANCIAL PRIVACY ACT

Sec.
47.1 Definitions.
47.2 Purpose.
47.3 Authorization.

47.4 Written request.
47.5 Certification.

AUTHORITY: 5 U.S.C. 301; 28 U.S.C. 509, 510; section 1108 of the Right to Financial Privacy Act of 1978, 12 U.S.C. 3408.

SOURCE: Order No. 822–79, 44 FR 14554, Mar. 13, 1979, unless otherwise noted.

§ 47.1 Definitions.

The terms used in this part shall have the same meaning as similar terms used in the Right to Financial Privacy Act of 1978. *Departmental unit* means any office, division, board, bureau, or other component of the Department of Justice which is authorized to conduct law enforcement inquiries. *Act* means the Right to Financial Privacy Act of 1978.

§ 47.2 Purpose.

The purpose of these regulations is to authorize Departmental units to request financial records from a financial institution pursuant to the formal written request procedure authorized by section 1108 of the Act, and to set forth the conditions under which such requests may be made.

§ 47.3 Authorization.

Departmental units are authorized to request financial records of any customer from a financial institution pursuant to a formal written request under the Act only if:

(a) No administrative summons or subpoena authority reasonably appears to be available to the Departmental unit to obtain financial records for the purpose for which the records are sought;

(b) There is reason to believe that the records sought are relevant to a legitimate law enforcement inquiry and will further that inquiry;

(c) The request is issued by a supervisory official of a rank designated by the head of the requesting Departmental unit. The officials so designated shall not delegate this authority to others;

(d) The request adheres to the requirements set forth in § 47.4; and

(e) The notice requirements set forth in section 1108(4) of the Act, or the requirements pertaining to delay of notice in section 1109 of the Act, are satisfied, except in situations (e.g., section 1113(g)) where no notice is required.

§ 47.4 Written request.

(a) The formal written request shall be in the form of a letter or memorandum to an appropriate official of the financial institution from which financial records are requested. The request shall be signed by the issuing official, and shall set forth that official's name, title, business address and business phone number. The request shall also contain the following:

(1) The identity of the customer or customers to whom the records pertain;

(2) A reasonable description of the records sought; and

(3) Such additional information as may be appropriate—e.g., the date on which the opportunity for the customer to challenge the formal written request will expire, the date on which the requesting Departmental unit expects to present a certificate of compliance with the applicable provisions of the Act, the name and title of the individual (if known) to whom disclosure is to be made.

(b) In cases where customer notice is delayed by court order, a copy of the court order shall be attached to the formal written request.

§ 47.5 Certification.

Prior to obtaining the requested records pursuant to a formal written request, an official of a rank designated by the head of the requesting Departmental unit shall certify in writing to the financial institution that the Departmental unit has complied with the applicable provisions of the Act.

PART 48—NEWSPAPER PRESERVATION ACT

Sec.
48.1 Purpose.
48.2 Definitions.
48.3 Procedure for filing all documents.
48.4 Application for approval of joint newspaper operating arrangement entered into after July 24, 1970.
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48.6 Public notice.