## Department of Health and Human Services

(f) Each applicant shall provide such information as the Assistant Secretary deems necessary to make a Federal assessment of the impact of the project on the quality of the human environment in accordance with section 102(2)(C) of the National Environmental Policy Act of 1969 (including the National Historical Preservation Act and other environmental acts). (42 U.S.C. 4332(2)(C)).

[42 FR 36149, July 13, 1977]

# Subpart C—Special Provisions

### §63.30 Scope of subpart.

This subpart sets forth supplemental special provisions which apply to all grants awarded by the Assistant Secretary.

## §63.31 Protection of human subjects.

All grants made pursuant to this part are subject to the specific provisions of Part 46 of this subtitle relating to the protection of human subjects.

#### §63.32 Data collection instruments.

(a) *Definitions.* For the purposes of this section "Child" means an individual who has not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which such research is to be conducted.

"Data-collection instruments" means tests, questionnaires, inventories, interview schedules or guides, rating scales, and survey plans or any other forms which are used to collect information on substantially identical items from 10 or more respondents.

"Respondents" means individuals or organizations from whom information is collected.

(b) *Applicability.* This section does not apply to instruments which deal solely with (1) functions of technical proficiency, such as scholastic aptitude or school achievement, or (2) routine demographic information.

(c) *Protection of privacy.* (1) No project supported under this part may involve the use of data collection instruments which constitute invasion of personal privacy through inquiries regarding such matters as religion, sex, race, or politics.

(2) A grantee which proposes to use a data collection instrument shall set forth in the grant application an explanation of the safeguards which will be used to restrict the use and disclosure of information so obtained to purposes directly connected with the project, including provisions for the destruction of such instruments where no longer needed for the purposes of the project.

(d) *Clearance of instruments.* (1) Grantees will not be required to submit datacollection instruments to the Assistant Secretary or obtain the Assistant Secretary's approval for the use of these instruments, except where the notification of grant award specifically so provides.

(2) If a grantee is required under paragraph (d)(1) of this section to submit data-collection instruments for the approval of the Assistant Secretary or if a grantee wishes the Assistant Secretary to review a data-collection instrument, the grantee shall submit seven copies of the document to the Assistant Secretary along with seven copies of the Office of Management and Budget's standard form No. 83 and seven copies of the Supporting Statement as required in the "Instructions for Requesting OMB Approval under the Federal Reports Act" (Standard form No. 83A).

(e) Responsibility for collection of information. A grantee shall not in any way represent or imply (either in a letter of transmittal, in the data-gathering instruments themselves, or in any other manner) that the information is being collected by or for the Federal Government or any department, agency or instrumentality thereof. Basic responsibility for the study and the data-gathering instruments rests with the grantee.

(f) Parental consent. In the case of any survey using data-collection instruments in which children are involved as respondents, the grantee, in addition to observing the other requirements contained in this section, and in Part 46 of this subtitle as appropriate, shall provide assurances satisfactory to the Assistant Secretary that informed consent will be obtained from the parents of each such respondent prior to the use of such instruments, except that a waiver from the requirements of this