

# Application for Federal Education Assistance

Note: If available, please provide application package on diskette and specify the file format.



U.S. Department of Education

Form Approved  
OMB No. 1875-0106  
Exp. 06/30/2001

## Applicant Information

**1. Name and Address**

Legal Name: \_\_\_\_\_

Address: \_\_\_\_\_

City

State

County

ZIP Code + 4

Organizational Unit

2. Applicant's D-U-N-S Number

3. Catalog of Federal Domestic Assistance #:  8  4         Title: \_\_\_\_\_

4. Project Director: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code + 4

Tel. #: ( ) - - Fax #: ( ) - -

E-Mail Address: \_\_\_\_\_

6. Type of Applicant (Enter appropriate letter in the box.)

- A State
- B County
- C Municipal
- D Township
- E Interstate
- F Intermunicipal
- G Special District
- H Independent School District
- I Public College or University
- J Private, Non-Profit College or University
- K Indian Tribe
- L Individual
- M Private, Profit-Making Organization
- N Other (Specify): \_\_\_\_\_

5. Is the applicant delinquent on any Federal debt?  Yes  No  
(If "Yes," attach an explanation.)

7. Novice Applicant  Yes  No

## Application Information

8. Type of Submission:

—PreApplication

—Application

Construction

Construction

Non-Construction

Non-Construction

9. Is application subject to review by Executive Order 12372 process?

Yes (Date made available to the Executive Order 12372 process for review): \_\_\_\_/\_\_\_\_/\_\_\_\_

No (If "No," check appropriate box below.)

Program is not covered by E.O. 12372.

Program has not been selected by State for review.

11. Are any research activities involving human subjects planned at any time during the proposed project period?  Yes  No

a. If "Yes," Exemption(s) #: \_\_\_\_\_

b. Assurance of Compliance #: \_\_\_\_\_

OR

c. IRB approval date: \_\_\_\_\_

Full IRB or

Expedited Review

12. Descriptive Title of Applicant's Project:

10. Proposed Project Dates: \_\_\_\_/\_\_\_\_/\_\_\_\_

Start Date:

End Date:

## Estimated Funding

13a. Federal	\$	.00
b. Applicant	\$	.00
c. State	\$	.00
d. Local	\$	.00
e. Other	\$	.00
f. Program Income	\$	.00
g. TOTAL	\$	.00

## Authorized Representative Information

14. To the best of my knowledge and belief, all data in this preapplication/application are true and correct. The document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached assurances if the assistance is awarded.

a. Typed Name of Authorized Representative

b. Title

c. Tel. #: ( ) - - Fax #: ( ) - -

d. E-Mail Address:

e. Signature of Authorized Representative

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Instructions for ED 424

- 1. Legal Name and Address.** Enter the legal name of applicant and the name of the primary organizational unit which will undertake the assistance activity.
- 2. D-U-N-S Number.** Enter the applicant's D-U-N-S Number. If your organization does not have a D-U-N-S Number, you can obtain the number by calling 1-800-333-0505 or by completing a D-U-N-S Number Request Form. The form can be obtained via the Internet at the following URL: <http://www.dnb.com/dbis/aboutdb/intlduns.htm>.
- 3. Catalog of Federal Domestic Assistance (CFDA) Number.** Enter the CFDA number and title of the program under which assistance is requested.
- 4. Project Director.** Name, address, telephone and fax numbers, and e-mail address of the person to be contacted on matters involving this application.
- 5. Federal Debt Delinquency.** Check "Yes" if the applicant's organization is delinquent on any Federal debt. (This question refers to the applicant's organization and not to the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.) Otherwise, check "No."
- 6. Type of Applicant.** Enter the appropriate letter in the box provided.
- 7. Novice Applicant.** Check "Yes" only if assistance is being requested under a program that gives special consideration to novice applicants and you meet the program requirements for novice applicants. By checking "Yes" the applicant certifies that it meets the novice applicant requirements specified by ED. Otherwise, check "No."
- 8. Type of Submission.** Self-explanatory.
- 9. Executive Order 12372.** Check "Yes" if the application is subject to review by Executive Order 12372. Also, please enter the month, date, and four (4) digit year (e.g., 12/12/2000). Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. Otherwise, check "No."
- 10. Proposed Project Dates.** Please enter the month, date, and four (4) digit year (e.g., 12/12/2000).
- 11. Human Subjects.** Check "Yes" or "No". If research activities involving human subjects are **not** planned **at any time** during the proposed project period, check "No." **The remaining parts of item 11 are then not applicable.**

If research activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, **are** planned **at any time** during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes." If **all** the research activities are designated to be exempt under the regulations, enter, in item 11a, the exemption number(s) corresponding to one or more of the six exemption categories listed in "Protection of Human Subjects in Research" attached to this form. Provide sufficient information in the application to allow a determination that the designated exemptions in item 11a, are appropriate. **Provide this narrative information in an "Item 11/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page. Skip the remaining parts of item 11.**

If **some or all** of the planned research activities involving human subjects are covered (nonexempt), skip item 11a and continue with the remaining parts of item 11, as noted below. In addition, follow the instructions in "Protection of Human Subjects in Research" attached to this form to prepare the six-point narrative about the nonexempt activities. **Provide this six-point narrative in an "Item 11/Protection**

**of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

**If the applicant organization has an approved Multiple Project Assurance of Compliance** on file with the Grants Policy and Oversight Staff (GPOS), U.S. Department of Education, or with the Office for Protection from Research Risks (OPRR), National Institutes of Health, U.S. Department of Health and Human Services, that covers the specific activity, enter the Assurance number in item 11b and the date of approval by the Institutional Review Board (IRB) of the proposed activities in item 11c. This date must be no earlier than one year before the receipt date for which the application is submitted and must include the four (4) digit year (e.g., 2000). Check the type of IRB review in the appropriate box. An IRB may use the expedited review procedure if it complies with the requirements of 34 CFR 97.110. If the IRB review is delayed beyond the submission of the application, enter "Pending" in item 11c. If your application is recommended/selected for funding, a follow-up certification of IRB approval from an official signing for the applicant organization must be sent to and received by the designated ED official within 30 days after a specific formal request from the designated ED official. **If the applicant organization does not have** on file with GPOS or OPRR **an approved Assurance of Compliance** that covers the proposed research activity, enter "None" in item 11b and skip 11c. In this case, the applicant organization, by the signature on the application, is declaring that it will comply with 34 CFR 97 within 30 days after a specific formal request from the designated ED official for the Assurance(s) and IRB certifications.

- 12. Project Title.** Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
- 13. Estimated Funding.** Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate **only** the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 13.
- 14. Certification.** To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office.

Be sure to enter the telephone and fax number and e-mail address of the authorized representative. Also, in item 14e, please enter the month, date, and four (4) digit year (e.g., 12/12/2000) in the date signed field.

### Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **1875-0106**. The time required to complete this information collection is estimated to average between 15 and 45 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the estimate(s) or suggestions for improving this form, please write to:** U.S. Department of Education, Washington, D.C. 20202-4651. **If you have comments or concerns regarding the status of your individual submission of this form write directly to:** Joyce I. Mays, Application Control Center, U.S. Department of Education, 7th and D Streets, S.W. ROB-3, Room 3633, Washington, D.C. 20202-4725.

# PROTECTION OF HUMAN SUBJECTS IN RESEARCH

## (Attachment to ED 424)

### I. Instructions to Applicants about the Narrative Information that Must be Provided if Research Activities Involving Human Subjects are Planned

If you marked item 11 on the application “Yes” and designated exemptions in 11a, **(all research activities are exempt)**, provide sufficient information in the application to allow a determination that the designated exemptions are appropriate. Research involving human subjects that is exempt from the regulations is discussed under **II.B. “Exemptions,”** below. The Narrative must be succinct. **Provide this information in an “Item 11/Protection of Human Subjects Attachment” and insert this attachment immediately following the ED 424 face page.**

If you marked “Yes” to item 11 on the face page, and designated no exemptions from the regulations **(some or all of the research activities are nonexempt)**, address the following six points for each nonexempt activity. In addition, if research involving human subjects will take place at collaborating site(s) or other performance site(s), provide this information before discussing the six points. Although no specific page limitation applies to this section of the application, be succinct. Provide the six-point narrative and discussion of other performance sites in an **“Item 11/Protection of Human Subjects Attachment” and insert this attachment immediately following the ED 424 face page.**

(1) Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

(2) Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(3) Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the cir-

cumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

(4) Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

(5) Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(6) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

### II. Information on Research Activities Involving Human Subjects

#### A. Definitions.

A research activity involves human subjects if the activity is research, as defined in the Department’s regulations, and the research activity will involve use of human subjects, as defined in the regulations.

#### —Is it a research activity?

The ED Regulations for the Protection of Human Subjects, Title 34, Code of Federal Regulations, Part 97, define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” *If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.* Activities which meet this definition constitute research 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.

## —Is it a human subject?

The regulations define human subject as “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.” (1) *If an activity involves obtaining information about a living person by manipulating that person or that person’s environment, as might occur when a new instructional technique is tested, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met.* (2) *If an activity involves obtaining private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information), the definition of human subject is met.* [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 school health record).]

## B. Exemptions.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories of *exemptions* are not covered by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) 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: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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. *If the subjects are children, this exemption applies only to research involving educational tests or observations of pub-*

*lic behavior when the investigator(s) do not participate in the activities being observed.* [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

(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 section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or 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 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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) 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, (a) if wholesome foods without additives are consumed or (b) 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.

*Copies of the Department of Education’s Regulations for the Protection of Human Subjects, 34 CFR Part 97 and other pertinent materials on the protection of human subjects in research are available from the Grants Policy and Oversight Staff (GPOS) Office of the Chief Financial and Chief Information Officer, U.S. Department of Education, Washington, D.C., telephone: (202) 708-8263, and on the U.S. Department of Education’s Protection of Human Subjects in Research Web Site at <http://ocfo.ed.gov/humansub.htm>.*