

## Definitions for Form ED 424

**Novice Applicant** (See 34 CFR 75.225). For discretionary grant programs under which the Secretary gives special consideration to novice applications, a novice applicant means any applicant for a grant from ED that—

- Has never received a grant or subgrant under the program from which it seeks funding;
- Has never been a member of a group application, submitted in accordance with 34 CFR 75.127-75.129, that received a grant under the program from which it seeks funding; and
- Has not had an active discretionary grant from the Federal government in the five years before the deadline date for applications under the program. For the purposes of this requirement, a grant is active until the end of the grant's project or funding period, including any extensions of those periods that extend the grantee's authority to obligate funds.

In the case of a group application submitted in accordance with 34 CFR 75.127-75.129, a group includes only parties that meet the requirements listed above.

**Type of Submission.** "Construction" includes construction of new buildings and acquisition, expansion, remodeling, and alteration of existing buildings, and initial equipment of any such buildings, or any combination of such activities (including architects' fees and the cost of acquisition of land). "Construction" also includes remodeling to meet standards, remodeling designed to conserve energy, renovation or remodeling to accommodate new technologies, and the purchase of existing historic buildings for conversion to public libraries. For the purposes of this paragraph, the term "equipment" includes machinery, utilities, and built-in equipment and any necessary enclosures or structures to house them; and such term includes all other items necessary for the functioning of a particular facility as a facility for the provision of library services.

**Executive Order 12372.** The purpose of Executive Order 12372 is to foster an intergovernmental partnership and strengthen federalism by relying on State and local processes for the coordination and review of proposed Federal financial assistance and direct Federal development. The application notice, as published in the Federal Register, informs the applicant as to whether the program is subject to the requirements of E.O. 12372. In addition, the application package contains information on the State Single Point of Contact. An applicant is still eligible to apply for a grant or grants even if its respective State, Territory, Commonwealth, etc. does not have a State Single Point of Contact. For additional information on E.O. 12372 go to <http://www.cfda.gov/public/EO12372.htm>.

## PROTECTION OF HUMAN SUBJECTS IN RESEARCH

### I. Definitions and Exemptions

#### 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.

#### —Research

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, 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.

#### —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, exemption 2 applies only to research involving educational tests and observations of public behavior when the investigator(s) do not participate in the