

**DEFINITIONS FOR
DEPARTMENT OF EDUCATION SUPPLEMENTAL INFORMATION FOR SF 424**

(Attachment to Instructions for Supplemental Information for SF 424)

Definitions:

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.

1. 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 that 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 activities being observed.***

Exemption 2 does not apply if children are surveyed or interviewed or if the research involves observation of public behavior and the investigator(s) 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.

II. Instructions for Exempt and Nonexempt Human Subjects Research Narratives

If the applicant marked “Yes” for Item 3 of Department of Education Supplemental Information for SF 424, the applicant must provide a human subjects “exempt research” or “nonexempt research” narrative. Insert the narrative(s) in the space provided. If you have multiple projects and need to provide more than one narrative, be sure to label each set of responses as to the project they address.

A. Exempt Research Narrative.

If you marked “Yes” for item 3 a. and designated exemption number(s), provide the “exempt research” narrative. The narrative must contain sufficient information about the involvement of human subjects in the proposed research to allow a determination by ED that the designated exemption(s) are appropriate. The narrative must be succinct.

B. Nonexempt Research Narrative.

If you marked “No” for item 3 a. you must provide the “nonexempt research” narrative. The narrative must address the following seven points. Although no specific page limitation applies to this section of the application, be succinct.

(1) Human Subjects Involvement and Characteristics: 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) Sources of Materials: 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) Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances 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) Potential Risks: 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) Protection Against Risk: 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) Importance of the Knowledge to be Gained: Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. 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.

(7) Collaborating Site(s): If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.

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 U.S. Department of Education, Protection of Human Subjects Coordinator, Office of the

*Chief Financial Officer, LBJ Building, 400 Maryland Avenue, SW, Washington, D.C. 20202-4250, telephone: (202) 260-3353, and on the U.S. Department of Education's Protection of Human Subjects in Research Web Site:
<http://www.ed.gov/about/offices/list/ocfo/humansub.html>*

NOTE: The **State Applicant Identifier** on the SF 424 is for State Use only. Please complete it on the OMB Standard 424 in the upper right corner of the form (if applicable).