Instructions for U.S. Department of Education
Supplemental Information for the SF-424

1. Project Director. Name, address, telephone and fax numbers, and e-mail address of the person to be contacted on matters involving this application. Items marked with an asterisk (*) are mandatory.

2. Novice Applicant. Check "Yes" if you meet the definition for novice applicants specified in the regulations in 34 CFR 75.225 and included on the attached page entitled "Definitions for U.S. Department of Education Supplemental Information for the SF-424"). By checking "Yes" the applicant certifies that it meets these novice applicant requirements. Check "No" if you do not meet the definition for novice applicants**.**

This novice applicant information will be used by ED to: 1) determine the amount and type of technical assistance that a novice might need, if funded, and 2) determine novice applicant eligibility in discretionary grant competitions that give special consideration to novice applications. Certain ED discretionary grant programs give special consideration to novice applications, either by establishing a special competition for novice applicants or by giving competitive preference to novice applicants under the procedures in 34 CFR 75.105(c)(2). If special consideration is being given to novice applications under a particular discretionary grant competition, the application notice for the competition published in the Federal Register will specify this information

3. Human Subjects Research. (See I. A. "Definitions" in attached page entitled "Definitions for U.S. Department of Education Supplemental Information for the SF-424.")

3a. If Not Human Subjects Research. Check "**No**" if research activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of Item 3 are then not applicable.

3a. If Human Subjects Research. Check "**Yes**" if research activities involving 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**" even if the research is exempt from the regulations for the protection of human subjects. (See I. B. "Exemptions" in attached page entitled "Definitions for U.S. Department of Education Supplemental Information for SF-424.")

3b. If Human Subjects Research is Exempt from the Human Subjects Regulations. Check "**Yes**" if all the research activities proposed are designated to be exempt from the regulations. Check the exemption number(s) corresponding to one or more of the eight exemption categories listed in I. B. "Exemptions." In addition, follow the instructions in II. A. "Exempt Research Narrative" in the attached page entitled "Definitions for U.S. Department of Education Supplemental Information for the SF-424."

3b. If Human Subjects Research is Not Exempt from Human Subjects Regulations. Check "**No**" if some or all of the planned research activities are covered (not exempt). In addition, follow the instructions in II. B. "Nonexempt Research Narrative" in the attached page entitled "Definitions for U.S. Department of Education Supplemental Information for the SF-424."

3b. Human Subjects Assurance Number. If the applicant has an approved Federal Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, that covers the specific activity, insert the number in the space provided. **(A list of current FWAs is available at: http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc)** If the applicant does not have an approved assurance on file with OHRP, enter "None." In this case, the applicant, by signature on the SF-424, is declaring that it will comply with 34 CFR 97 and proceed to obtain the human subjects assurance upon request by the designated ED official. If the application is recommended/selected for funding, the designated ED official will request that the applicant obtain the assurance within 30 days after the specific formal request.

3c. If applicable, please attach your "Exempt Research" or "Nonexempt Research" narrative to your submission of the U.S Department of Education Supplemental Information for the SF-424 form as instructed in item II, "Instructions for Exempt and Nonexempt Human Subjects Research Narratives" in the attached page entitled "Definitions for U.S. Department of Education Supplemental Information for the SF-424."

Note about Institutional Review Board Approval. ED does not require certification of Institutional Review Board approval with the application. However, if an application that involves non-exempt human subjects research is recommended/selected for funding, the designated ED official will request that the applicant obtain and send the certification to ED within 30 days after the formal request.
No covered human subjects research can be conducted until the study has ED clearance for protection of human subjects in research.

Public 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. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The obligation to respond to this collection is required to obtain or retain benefit (20 USC 3474 General Education Provisions Act). Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, 400 Maryland Ave., SW, Washington, DC 20210-4537 or email ICDocketMgr@ed.gov and reference the OMB Control Number 1894-0007. Note: Please do not return the completed ED SF 424 Supplemental Form to this address.

Definitions for U.S. Department of Education
Supplemental Information for the SF-424

Definitions:

Novice Applicant (See 34 CFR 75.225)

For discretionary grant programs, 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.

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. 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 (i) information or biospecimens through intervention or interaction with the individual and uses through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (ii) obtains, uses, studies, analyzes, or generate identifiable private information or identifiable biospecimens. "

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. If an activity involves obtaining private information about a living person in such a way that the information can be ***directly or indirectly*** *linked to that individual), 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 eight categories of ***exemptions*** are not covered by the regulations:

(1) Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. ***If an educational practice is being introduced to the site and is not widely used for similar populations, it is not covered by this exemption***.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recordings) if at least one of the following criteria is met: (i) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing,

employability, educational advancement or reputation; or (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a "limited IRB review" to make the determinations required by 34 CFR 97.111(a)(7).

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 benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject' financial standing, employability, educational advancement or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 34 CFR 97.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subject play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary Research for which Consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is men: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) the research involves only information collection and analysis involving the investigators' use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512 (b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 USC 3501 note, if all of the identifiable private information collected, used or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 USC 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 USC 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternative to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(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.

(7) Storage or Maintenance for Secondary Research for which Broad Consent is required. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations requires by 34 CFR 97.111(a)(8).

(8) Secondary Research for which Broad Consent is Required. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if the following criteria are met: (i) Broad Consent for the storage, maintenance and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 34 CFR 97.116(a) (1)-(4), (a) (6) and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 34 CFR 97.117. (iii) an IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not prevent an investigator from abiding by any legal requirements to return individual research results.

II. Instructions for Exempt and Nonexempt Human Subjects Research Narratives

If the applicant marked "Yes" for Item 3.b. of the U.S. Department of Education Supplemental Information for the SF 424, the applicant must attach a human subjects "exempt research" or "nonexempt research" narrative to the U.S. Department of Education Supplemental Information for the SF-424 form. If you have multiple projects, include information about each, labeling the responses as to the project they address. For applications that include multiple research projects this can be done in a single narrative or in more than one narrative as appropriate.

A. Exempt Research Narrative.
If you marked "Yes" for item 3.b. and designated exemption numbers(s), attach the "exempt research" narrative to the U.S. Department of Education Supplemental Information for the SF-424. 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.b. you must attach the "nonexempt research" narrative to the U.S. Department of Education Supplemental Information for the SF-424. 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 Office of the Chief Financial Officer, U.S. Department of Education, Washington, D.C. 20202-4331, telephone: (202) 245-8090, 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 SF-424 in the upper right corner of the form (if applicable).